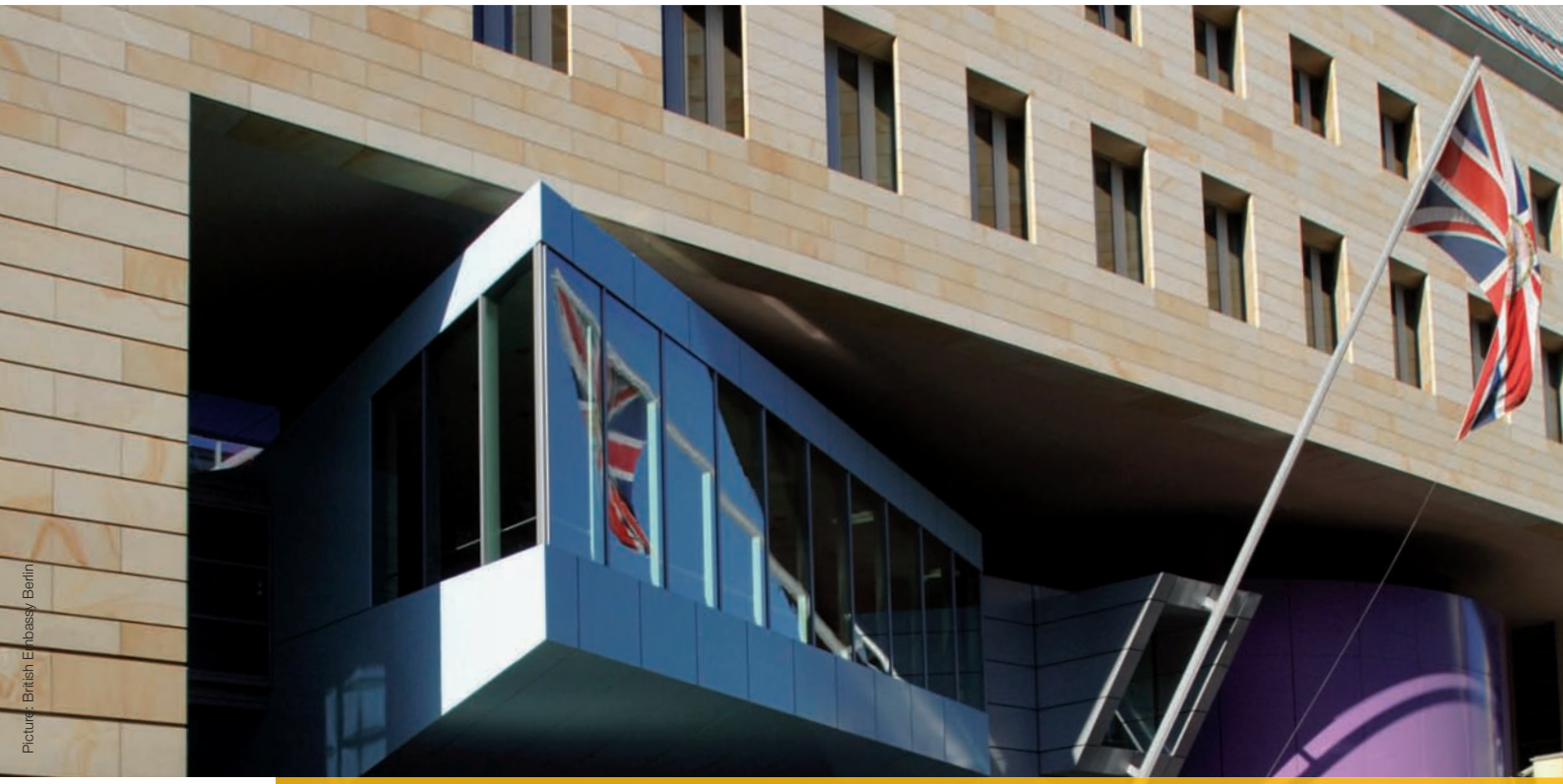
BIOCOM Event

10th Berlin Conference on Life Sciences

Novel Antimicrobials



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Wanted: Novel Antimicrobials

Healthcare systems worldwide are in growing need of efficiently combating antimicrobial resistance (AMR). Solutions for finding novel antibiotics or effective alternative strategies are therefore urgently wanted, but a highly debated issue amongst experts in the pharma and biotech sector. From a business perspective, the ups and downs of pharma evolvement demonstrate the highly challenging market conditions in which it operates. On the other hand, there are dozens of small and medium-sized companies as well as academic groups working on new drugs for bad bugs, particularly in Europe. In addition, policy makers worldwide have put the topic on high priority and set up funding strategies to help advance the field.

In this setting, several questions arise on the agenda of major stakeholders in Europe: Who is investing in novel antibiotics? Which business models are appropriate? Which funding strategies help accelerate R&D in the field? Which technologies are the most promising – on the company side, but also in the academic area?

These aspects will be among those that will be discussed during the ***"10th Berlin Conference on Life Sciences – Novel Antimicrobials"***, to which German information specialist BIOCOM AG and the Department of International Trade of the United Kingdom together with further partners such as the BEAM Alliance and the European Biotechnology Network are pleased to invite in the British Embassy in Berlin.

Several sessions with more than 30 top-class speakers will cover all the different aspects of AMR and potential strategies to combat it efficiently. Antibiotics experts, drug developers and microbiologists from European biotech and pharma companies as well as researchers, entrepreneurs, market specialists, investors and start-ups will shed light on this challenging market from a European perspective.

10 years in a nutshell

The “Berlin Conference on Life Sciences” has developed an unparalleled profile over the course of its ten-year history. Each year, BIOCOM AG showcased a different topic of strategic value to critical areas in the life sciences sector, discussing challenges from R&D to market access. Since the beginning in 2008 in the British Embassy, the Berlin Conference opened the meetings season in February and presented high-level speakers in an exclusive international atmosphere in the German capital. With the tenth conference and its focus on novel antimicrobials, we thus return to the location where it all began in 2008. Regarding our topics, we covered a highly diverse range – from biomarkers and rare diseases to antibodies and companion diagnostics as well as clinical trials, life cycle management and big data or areas such as natural products and digital health.

2008
1st Berlin Conference
Smart Clinical Trials
British Embassy

2009
2nd Berlin Conference
From Biomarkers to Diagnostics
Canadian Embassy

2010
3rd Berlin Conference
Effective Life Cycle Management
Belgian Embassy

2011
4th Berlin Conference
Rare Diseases – Blockbusters in the Niche
Embassy of Spain

2012
5th Berlin Conference
Immune Therapies
Swiss Embassy

BIOCOM Event

7th Berlin Conference
Big Data – Big Drugs
The Nordic Embassies

9th Berlin Conference
Digital Health Solutions
French Embassy

2013 2014 2015 2016 2017

6th Berlin Conference
Companion Diagnostics
Embassy of the Netherlands

8th Berlin Conference
Natural Products
Embassy of South Africa

10th Berlin Conference
Novel Antimicrobials
British Embassy

Programme

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9:30	Welcome Address **Sir Sebastian Wood KCMG** British Ambassador to Germany	20
	Keynote Session Moderator: Peter West, AIM, UK | Room: Conference drum	
9:45	Keynote: The Global AMR Innovation Fund **Christopher Egerton-Warburton** Fund Manager and Founding Partner of Lion's Head Global Partner and Member of Expert Advisory Bord, Global AMR Innovation Fund, UK	22
10:10	Stimulating innovation: Novel approaches to incentivising antibacterial R&D **David Findlay** Deputy Coordinator Drive-AB/GSK, UK	30
10:30	Funding the research and development of novel antibiotics: The perspective of a start-up company **Nicholas Benedict** Co-Founder & CEO, Allecra, GER	36
10:50	Coffee Break	

Time		Page	Time		Page
	Session: "Market access in the era of AMR – bringing ideas to the patients" Moderator: Peter West, AIM, UK | Room: Conference drum	44		Session: "SMEs to tackle AMR" (Information center) Chair: Philippe Villain-Guillot, Nosopharm, F Room: Information center	62
11:10	Compulsory licenses – bliss or doom for pharmaceutical industry **Ute Kilger** Partner, BOEHMERT & BOEHMERT, Berlin, GER	46	11:10	**Philippe Villain-Guillot** CEO, Nosopharm, F	63
11:25	IP & Regulation: Patent strategies to meet the challenge of AMR **Heinz Goddar** Partner, BOEHMERT & BOEHMERT, Munich, GER	50	11:30	**Leonie de Best** CBO, Madam Therapeutics, NL	64
11:40	From bench to bedside: Developing new drugs for bad bugs on a European scale **Anders Karlén** Professor, University of Uppsala & Managing Coordinator, ENABLE consortium, SE	54	11:50	**Nicola Thompson** CBO, PhicoTherapeutics, UK	65
12:00	Clinical decision making: The relevance of new methods for antimicrobial susceptibility testing **Hajo Grundmann** Professor, University of Groningen, Member of EUCAST Subcommittee, NL	58	12:10	**Marc Lemonnier** CEO, Antabio, F	66
12:20	Panel discussion – How to overcome the bottlenecks in the AMR field? **Christopher Egerton-Warburton** Member of Expert Advisory Bord, Global AMR Innovation Fund, UK **Andrew Ullmann** Professor, University of Würzburg, GER **Ute Kilger** Boehmert & Boehmert, GER **Hajo Grundmann** Professor, University of Groningen, NL		12:30	**Thomas Kapsner** CEO, Morphochem, GER	67
12:50	Lunch Break				

Programme

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13:40	Public-private partnerships to accelerate the devlopment of antimicrobial drugs **Peter Jackson** Steering group chairman, AMR centre, UK	70	13:40	**Yves Briers** Professor, Ghent University, BE	86
14:00	The SME perspective **Marie Petit** Coordinator BEAM Alliance	74	14:00	**Stephan Sieber** Professor, Technical University Munich, GER	88
	The BioVersys case **Marc Gitzinger** CEO, BioVersys, CH	75	14:20	**Michael McDonough** Senior Post-doc, University of Oxford, UK	90
14:30	Technology Highlights – Company presentations **Rasmus Toft-Kehler** CEO, AntibioTx, DK	80	14:40	**Mark Brönstrup** Professor, Helmholtz Centre for Infection Research, GER	92
	Deborah O'Neil CEO & CSO, NovaBiotics, UK	81	15:00	**Andreas Peschel** Professor, University of Tübingen, GER	94
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16:10	Investors talk – Panel discussion: Developing new antimicrobial agents – a business case for start-ups? **Rasmus Toft-Kehler** CEO, AntibioTx, DK **Holger Reithinger** Partner, Forbion Capital Partners, GER/NL **Olivier Litzka** Partner, Edmond de Rothschild, F **Marc Gitzinger** CEO, BioVersys, CH	100			
16:40	Start-up pitch: Start-up presentations and award Auspherix, UK Immunethep, P QureTech Bio, S Juvabis, CH Omnix Medical, ISR	103			
17:20	Open discussion and wrap-up: The future of anti-infective R&D				
17:40	Networking & reception				

Moderator: **Peter West**, CEO, Academy of Infection Management (AIM), UK

Life Sciences
The UK Advantage

In the UK, partners work together to support a research and innovation culture that spans sectors and geographies, and supports the creation of a fully integrated life science and healthcare ecosystem that places the patient at the heart of the system. The UK has a clear advantage from a global perspective in the following key areas:

Dementia

An estimated 35 million people globally are living with dementia and this figure is set to double by 2030. With world-class research on disease mechanisms and early diagnosis, as well as specialist clinical networks to support translation and access to patients, the UK offer is compelling.

Digital Health and Care

Through 2018, the UK telecare market is expected to grow at a CAGR of 4-5%, telehealth at 13%, mHealth apps at 35% and mHealth wearables at 25%. The UK healthcare analytics market is forecast to grow at 22%, and digitised health systems at 6% per annum.

In the first assessment of the digital health sector in the UK, there are an estimated 7,400 employees at nearly 300 companies and a turnover of nearly £900m. This is the fastest growing subsector for employment with 23% annual growth rate over the last 5 years.

Experimental Medicine and Clinical Trials

The UK offers a fast, cost-effective and high quality location for experimental medicine and clinical research. This is supported by translational research expertise, unrivalled access to data and leading research facilities.

Clinical Research Networks are embedded in the NHS supporting the delivery of multicentre clinical studies with more than 3 million patients recruited over the last 6 years.

Medical Technology

There are more than 3,500 UK based MedTech companies employing over 115,000 individuals and generating a turnover of £21bn. With a thriving ecosystem of researchers, scientists, engineers, designers and NHS clinicians, coupled with a proven route to market for innovative technologies, the UK offer in this space is competitive.

Medicines Manufacturing

Tomorrow's medicines will demand an ever closer integration of development science and technology with manufacturing. The UK is the place to make them. The UK has a long track record of cost-effective and compliant medicines manufacturing from leading global companies and has specialised national networks run by Innovate UK in High Value Manufacturing (including centres of excellence in process innovation, biologics, and formulation), Cell and Gene Therapy, Digital Economy, and Precision Medicine. Operating as a consortium of centres they make world-leading technical capability available to businesses, and facilitate process development, prototyping, and scale-up.

Regenerative Medicine and Stem Cells

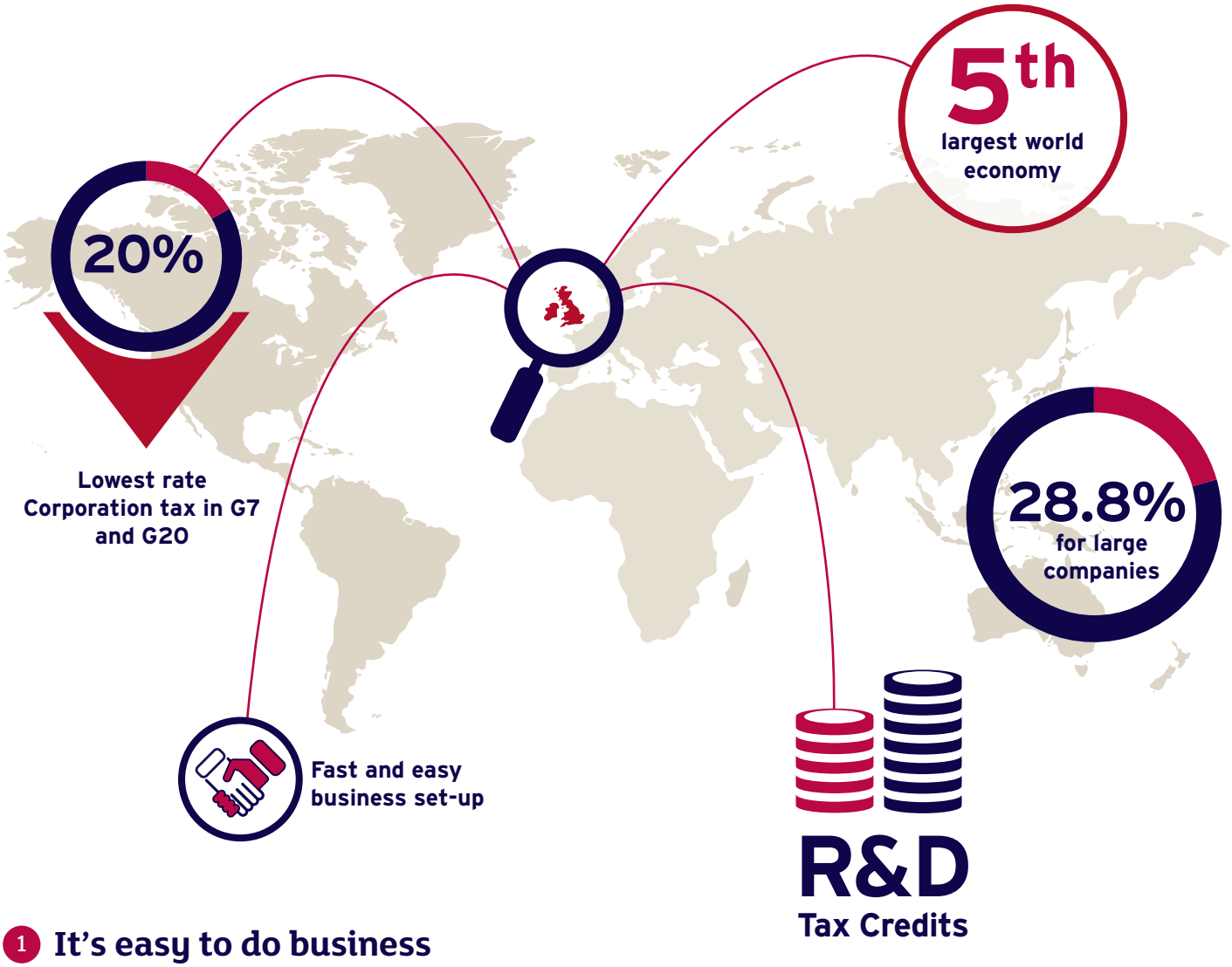
Regenerative medicine is one of the most exciting and promising areas of science and UK scientists have been involved since the outset. Europe has the second largest regenerative medicine ecosystem in the world with 400+ companies related to regenerative medicine. Nearly one in three SMEs active in Europe's Advanced Therapy Medicinal Product (ATMP) market are based in the UK.

Stratified Medicine

Globally, there is a growing demand for stratified medicines and companion diagnostics. With first class research and expertise, world leading data & translational infrastructure and an established value chain, the UK has a great deal to offer in this space.

UK Life Sciences
Top 5 Reasons to do Business

The UK has one of the most vibrant and productive life science sectors in the world. With over 5,600 companies, a proven track record of scientific achievement, and strong government commitment, the UK leads Europe in life science financing and is the number one choice for European HQs.



1 It's easy to do business

- **5th** largest world economy
- Leading European destination for VC and international HQs with **43%** of companies choosing to locate their EHQs in the UK
- Fast and easy business set-up
- Sensible regulation and labour law
- Corporation tax at **20%**...lowest rate in G7 and G20
- The Patent Box: A lower corporation tax of **10%** on qualifying profits
- R&D Tax Credits provide up to **46%** back on spending for SME's and R&D Expenditure Credit provides up to **28.8%** for large companies
- National and local funding for business growth and R&D.

2 World-class talent and 'human capital'

- A powerhouse with leading academic institutions
- **4** of the world's top **10** universities for clinical and health sciences
- **78** Nobel Prizes for contributions to biomedical science
- A highly skilled and flexible workforce of more than **222,000** people
- Research Councils invest **£3bn (US$4.6bn)** in research each year
- Research Charities fund over **£1bn (US$1.5bn)** of health research each year.

3 Networked for success

- The UK Government's two major initiatives, the **10 year** Strategy for Life Sciences and Innovation Health and Wealth – creating an environment of collaboration
- A dedicated Office for Life Sciences
- DIT Life Sciences Organisation (LSO) to help you invest in, and expand from, the UK
- Catapults – specialised national networks – in areas such as Precision Medicine, Cell and Gene Therapy and High Value Manufacturing
- **15** Academic Health Science Networks (AHSNs) in England, with streamlined NHS entry points for Scotland, Northern Ireland and Wales
- Research funders and charities committed to partnering with industry
- Full range of R&D, service and supply chain partners.

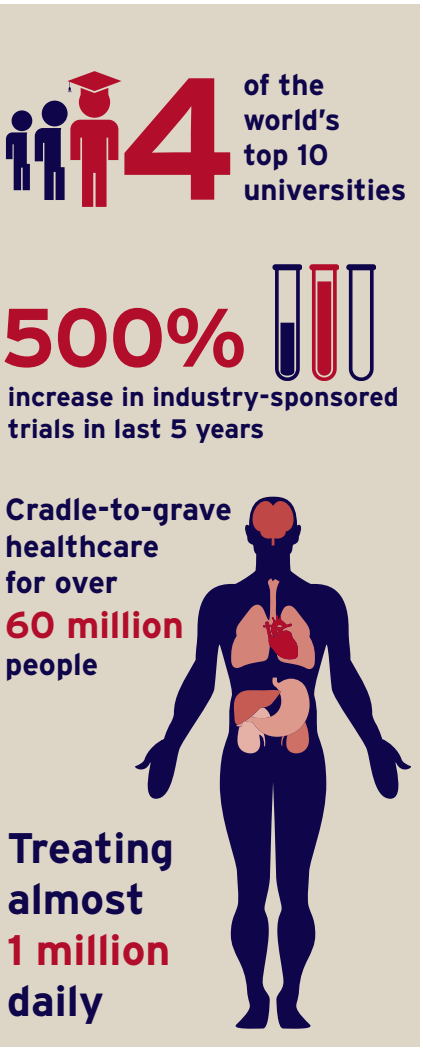
4 Infrastructure platform worth billions

- National health research infrastructure funded at more than **£1bn (US$1.5bn)** per year
- Clinical research network
- **35** first global patients last year in commercial contract studies
- More than **3 million** patients recruited over the last **6** years
- **500%** increase in industry-sponsored trials in last **5** years
- Unparalleled data - **100,000** Genomes Project – leading the world in whole genome sequencing and enabling genomic medicine
- UK Biobank with **500,000** participants
- Home to globally-respected regulators – MHRA and EMA
- A fast and supportive system for CE Marking
- Home to NICE - the world leader in health technology assessment.

5 The NHS as your platform for global success

- The world's largest healthcare system – the National Health Service (NHS)
- Free at point of use
- Cradle-to-grave healthcare for over **60 million** people
- Treating almost **1 million** daily
- Collecting real world data to improve care and fuel research
- Build a world-class and globally portable evidence base.

The UK offers a healthcare ecosystem to enable partnering between industry, NHS, and the research base placing the patient at the heart of the system.



Linking you to UK Life Sciences – www.lifesciences.ukti.gov.uk

A UK Life Sciences website has been launched to provide a single access point to the UK Life Sciences landscape. It provides an online platform to allow UK and international companies, associations, academia and R&D organisations to connect.

One of the key features of the site is access to a database of over 5,000 UK life science companies that are developing, producing and marketing products and services in the pharmaceutical, medical technology and medical biotechnology markets. You can gain access to company information by sector, specialism, business activity and location and connect to the UK landscape.

www.lifesciences.ukti.gov.uk

Global access

DIT's Life Sciences Organisation (LSO) can help you work with and establish new connections in the UK. Our combined network of government and private-sector specialists in the UK and in our British Embassies and Consulates in Europe and throughout the world offer practical advice and free and confidential support in connecting businesses to:

- Access to government incentives, tax breaks, regulatory and business planning issues
- Site and property search assistance and information on staff recruitment
- Key contacts and links with centres of excellence and leading organisations
- Relationship management and aftercare through on-going support

Once established in the UK, we can help companies take advantage of new business opportunities and branch out to new locations, both in the UK and overseas. The UK's excellent reputation in research, clinical development, health regulation, and health economics combined with DIT's own global connectivity mean that the UK can help businesses maximise the export potential of their health technologies, products or services.

www.gov.uk/dit | Twitter: @tradegovuk_LSO

Britain's economy is one of the strongest major advanced economies in the world, and is well placed to face the future. According to the IMF the UK is the fastest growing G7 economy. It is the fifth largest economy in the world and it attracts a fifth of all foreign investment in the EU. The UK remains a great trading nation and is open for business. It is the same outward-looking, globally-minded, big-thinking country that is has always been.

The United Kingdom and Germany are long-standing trade and investment partners. The close economic relation between both countries is also reflected in the many UK companies that are already successfully doing business in Germany, either as investors or as exporters, or German companies that are active in the UK.

Investing in and exporting from the UK

LSO is responsible for driving inward investment and enhancing exports in the sector. The team based in the UK and in our offices Embassies and Consulates around the world directly supports business to locate in the UK, or to export from the UK to new markets.

The network has landed more than 650 inward investment projects worth nearly £5bn in the last four years, of which a strong proportion are linked to value generating activity such as research and development, manufacturing, or exporting.

The UK is highly attractive for inward investment and remains the #1 destination in Europe for health and life sciences FDI.

In Germany, DIT has offices in Dusseldorf, Berlin and Munich. The Life Sciences Team is based in Dusseldorf.

For further information please contact:

Rachel Postert
Senior Business Development Manager
Tel: +49 (0)211 9448 155
Email: rachel.postert@mobile.trade.gov.uk

or

Dr. Liam Harris
Senior Campaign Manager
Tel: +49 (0)211 9448 206
Email: liam.harris@mobile.trade.gov.uk

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Department for International Trade

Department for International Trade (DIT) drives the government's policy of increasing the number of exporters and inward investors to the UK. DIT helps UK-based companies export and overseas companies bring their high-quality investment to the UK's dynamic economy. DIT provides companies with the tools and support they require to be competitive on the world stage.

Published in October 2016 by Department for International Trade

Examination of patent applications within 12 months – boon or bane?

Dr. Ute Kilger, Partner, Boehmert & Boehmert, Berlin, Germany

The European Patent Office (EPO) is currently pushing the project "Early Certainty" in order to speed up examination of patent applications. The aim is to complete examination within 12 months between request for examination and intent to grant the application or refusal. The EPO wants to give third parties and applicants early certainty whether a patent will be granted or refused. The EPO intends to hire many new and yet inexperienced examiners in order to achieve this goal. Efficiency of examination and legal certainty is the focus. The EPO wants to reach a unique position of being a top player in both quality and timelines.

At present the EPO has, however, already installed the PACE procedure. This means – upon request of the applicant the examination procedure may be accelerated. The PACE programme works excellently. Examination is also accelerated if a third party files observations. However, according to this new initiative all applications will be accelerated.

A 12 months prosecution timeline may cause problems. Sometimes it may be of great importance for the applicant to gain some time before the EPO decides finally on the application. If further data are needed in order to prove the alleged and credible effect it may be not feasible to create them in less than 12 months. Such a situation may lead to an early refusal of a great invention. An application can also contain many alternatives and lack unity. The applicant may need time in order to validate the most valuable embodiments of his invention. The filing of divisional applications in order to keep a case alive longer would be a very expensive strategy. Furthermore, once a patent is granted, high nationalisation costs have to be born by the applicant. A large number of biotech and pharma projects fail and it may be better if the application can be dropped before high nationalisation costs are due. For many applicants, especially small companies, this is an important reason to slow down prosecution in some cases. Thus, long product cycles and high risk of failure in the biotech and pharma area are probably not in line with a 12 months prosecution in each and every case. Instead of rapid prosecution it is probably preferable that applicants and examiners have sufficient time. An acceleration should be only sought after if necessary. The question thus arises whether the "Early Certainty" initiative is actually suited to enhance quality and certainty or whether applicants will face early refusals and/or more costs instead.

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Hollerallee 32
T +49 (421) 340 90

33605 Bielefeld
Detmolder Str. 235
T +49 (521) 304 36 60

40479 Dusseldorf
Jaegerstr. 21
T +49 (211) 71 17 00

60323 Frankfurt am Main
Freiherr-vom-Stein-Str. 7
T +49 (69) 74 34 62 0

24105 Kiel
Holtenauer Str. 57
T +49 (431) 23 95 210

80336 Munich
Pettenkoferstr. 22
T +49 (89) 55 96 80

14469 Potsdam
Helene-Lange-Str. 3
T +49 (331) 27 54 30

03002 Alicante
Explanada de España
1 – Principal, Spain
T +34 (965) 21 53 99

75009 Paris
21&23 Blvd. Haussmann
Actualis, Level 2, France
T +33 (1) 5603 6591

200021 Shanghai
1 Fuxing Zhong Lu
Suite 1208, China
T +86 (21) 6391 9290 ext 606

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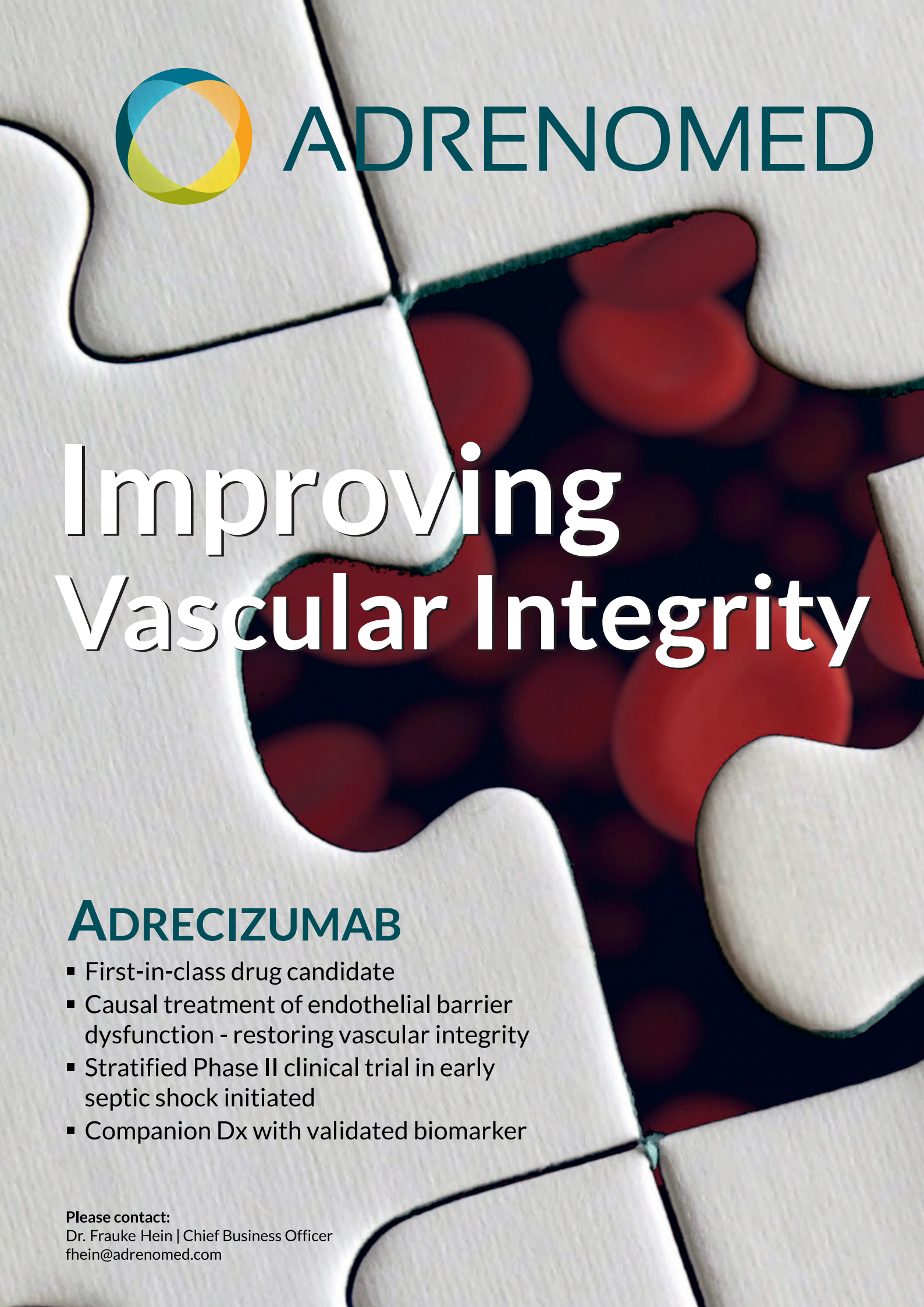

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fhein@adrenomed.com

Improving Survival

...in infections and beyond

Bundesministerium für Bildung und Forschung

Development of ADRECIZUMAB was supported by grants of the German Federal Ministry of Education and Research (BMBF)

We are a group of Biopharmaceutical companies from Europe innovating in Anti-Microbial resistance research

The emergence of multi-drug resistant bacteria presents a global public health crisis which demands the development of new antibiotics, preventive or alternative strategies, yet the R&D investment from large pharmaceutical companies is on the wane due to lack of attractiveness of investment in this therapeutic area. Innovation is thus largely driven by small and medium biopharma companies, and European nations need to engage more extensively in supporting this innovation via new policies and R&D stimulating incentives. The BEAM Alliance with its more than 50 members will work to improve the regulatory, investment, and commercial environments in Europe for research, development, approval and market viability of new products combating antimicrobial resistance.

Why Small and Medium-sized Enterprises (SMEs) research is important in the field of AMR?

The value chain of innovation in pharma is based on close interconnections between academics, biotech and big pharma players, each having its core activities on which they are expert and most cost-efficient. In recent years big pharma has generally withdrawn from the discovery and early-phase development of antibiotics.

In contrast, SMEs core activity is to generate valuable science and results, from discovery to clinical stage. They are laser-focused on R&D to address AMR and provide the juncture where public and private money comes together to support the same AMR goals.

Jim O'Neill's report highlights that to take action on AMR, 15 new antimicrobial medicines a decade should reach the market. Working back from this due to attrition, to achieve 15 compounds on the market, 300 early-stage projects are necessary. SMEs are the keystone to fuel this pipeline by providing new innovative compounds and technologies and conducting both early and clinical stage research.

From academic research to big pharma late clinical and market endorsement, SMEs are bridging this 6–10 years gap of R&D de-risking. This role of SME's is particularly important with AMR R&D as in the past decades all antibiotics that moved into late stage clinical development or received market approval went at some point of their development through the hands of SMEs.

SMEs are the crucial engine for any innovation and new products in AMR.

SMEs addressing AMR navigate in a sub-optimal environment. Why?

Due to limited innovation in the field over the last few decades, hospitals and re-imbursement infrastructures have for a long time managed patients' bacterial infection even resistant ones at cheap generic prices.

From USD 40bn antibiotics sold per year, less than 12% (USD 4.7bn) derive from patented drugs (according to the Jim O'Neill report). In both absolute and relative terms, this is very little. USD4-5bn is the annual sales of many stand-alone oncology, cardio, endocrinal or CNS drugs.

Bacterial infection management algorithms are based on generic drugs, empirical approach and mainly driven by the individual cost & benefit. Stewardship is at infancy. Besides, the issue of nosocomial infection is sensitive for hospitals and the information we would all need to better support their effort is underreported.

That makes this area of disease very unpredictable, unreliable and so far not sustainable for businesses who would like to invest in innovation.

What are SMEs major demands in this arena?

To tackle the growing threat of drug-resistant infections, we need this environment to take action differently and allow:

- Suitable, tailor-made regulatory guidance to perform adapted clinical trials for all approaches (small molecules, biologics, prophylaxis, diagnostics, immune-targeting, microbiome-based, phage-based therapies, anti-biofilm agents, transcriptional inhibitors …)
- Alignment of regulatory and payers toward the societal value of alternative compounds to combat AMR since they surpass the individual direct benefit.
- This alignment being translated into a specific designation (GAIN Act-like, QIPD-like), the reimbursement model and the infection management algorithm.

This is the stepping stone to reinvigorate innovation in this area.

We, SMEs have then a lot of work to do to foster R&D, attract and train a sufficiently talented workforce (to develop expertise in early stage, clinical stage, indications, trial design, manufacturing…) and thus repopulate the breadth of expertise that is missing from the therapeutic area after so many years of neglect.

Public support is also needed through a diversity of mechanisms to incentivize R&D in a manner that encourages private money to follow public one. Several mechanisms would help to improve the situation and attract more private capital back into the area:

- Grant funding dedicated to AMR drug development projects, from early research to clinical development. Grants should also allow for small focused groups rather than large consortia.
- Focused loan/venture fund initiatives to support SMEs combating AMR by co-investing with private capital into SMEs.
- Better valuation of AMR products reaching the market according to their societal value.

Moderation

Peter West

CEO

Academy of Infection Management (AIM) Ltd, Cheshire

Peter is the founder and Chief Executive Officer of a not-for-profit Infectious Disease society, the Academy of Infection Management, (AIM) Ltd., registered in the United Kingdom. AIM provides medical education resources for healthcare professionals with an interest in infectious disease and is supported by a global Faculty of some of the leading clinicians in this field. AIM works with other medical societies, the pharmaceutical industry and various government and regulatory authorities on programmes relating to infectious disease.

Peter's background is in the pharmaceutical industry where he has worked for over 25 years, specifically in the field of infectious disease. During this time, Peter held a number of senior Executive roles, including General Manager of AstraZeneca, Romania, and Senior Marketing Director for anti-infectives at Wyeth Pharmaceuticals, responsible for Europe, Middle East, Africa and Canada.

Since 2010, Peter has been working as a freelance consultant, providing strategic and operational support to small biotech and major pharmaceutical companies. His clients include, Astellas, Cubist/Merck, Basilea, Roche, Genentech, AstraZeneca, GSK and the U.K. Office of Health Economics (OHE).

Academy of Infection Management (AIM) Ltd.
BioHub at Alderley Park
Alderley Edge
Cheshire SK10 4TG
United Kingdom

Tel.: +44 7920 591 385
Mail: petewest@aiminfection.org

Sir Sebastian Wood KCMG

British Ambassador to Germany

British Embassy in Berlin

Sir Sebastian Wood took up his appointment as Her Majesty's Ambassador to Germany in September 2015. Before his current posting, he served as British Ambassador to China from 2010 to 2015.

Sebastian joined the Foreign and Commonwealth Office (FCO) in 1983. After a posting to the British Embassy in Bangkok, he learned Mandarin at the beginning of the 90s before serving as a First Secretary in the Sino-British Joint Liaison Group in Hong Kong from 1992 to 1996 in the run-up to the handover of Hong Kong. He was Political Counsellor in Washington from 2001 to 2005 following US foreign policy in Asia. From 2005 to 2008 he was the FCO's Asia-Pacific Director before undertaking a one year secondment to Rolls-Royce from 2008 to 2009.

Prior to joining the FCO, Sebastian studied Mathematics and Philosophy at Magdalen College, Oxford. Sebastian is married with four children.

In 2014, he was appointed Knight Commander of the Order of St Michael and St George (KCMG) for services to British prosperity and British interests in China.

He speaks German, English, Mandarin and Thai.

British Embassy Berlin

British Embassy in Berlin
Wilhelmstraße 70/71
10117 Berlin
Germany

Tel.: +49 30 204 570
ukingermany@fco.gov.uk

Welcome address

It is my great pleasure to host the 10th Berlin Conference on Life Sciences, which you are attending today at the British Embassy in Berlin. The Berlin Conferences started here 10 years ago, so I am delighted that BIOCOM has returned to the British Embassy for this anniversary. Today's conference has been organised in partnership between BIOCOM and the UK's Department for International Trade (DIT).

We are delighted to host such a large group of experts to discuss the challenges of developing new antimicrobials to tackle the complex problem of antimicrobial resistance (AMR). The UK has been at the centre of developing solutions to this problem for many years.

According to the UK's AMR Review, at least 700,000 people across the world die each year of drug resistance in illnesses such as bacterial infections, malaria, HIV/Aids or tuberculosis. By 2050 drug-resistant infections could cause 10 million deaths a year around the globe. Despite this, the authorisation of new antibiotics in recent years has fallen dramatically. Interest from industry into the development of new antimicrobial drugs is low and pipelines are in urgent need of replenishment. An entirely new approach to the development of new drug candidates from the biotech and pharma sectors as well as from academia is essential. Today's conference will explore this exciting market and the challenging conditions for the development of novel antimicrobials.

Stopping superbugs is a global public good that cannot be tackled by any country acting alone. Yet they can be beaten with political leadership and global coordination between governments, industry and academia. In the UK, understanding and tackling AMR is a key priority and we have been at the forefront in putting AMR securely on the international agenda.

I am delighted we have so many distinguished speakers today from the UK and from around the world. I hope that today's conference will lead to some exciting new collaborations across the disciplines and countries represented here.

The Global AMR Innovation Fund

Christopher Egerton-Warburton

Partner

Lion's Head Global Partners, London

Christopher Egerton-Warburton – or "Edge" is a Founding Partner of Lion's Head Global Partners, a London-based merchant bank that provides advisory, financial structuring, capital raising and asset management services, specialising in the development sector.

Prior to establishing Lion's Head in 2008, Edge spent 14 years at Goldman Sachs within the Debt Capital Markets group. In his last role, he was Head of the Sovereign, Supranational and Agency team. He was instrumental in the creation of a new multilateral development institution – the International Finance Facility for Immunisation (IFFIm), which brings together Gavi (the Global Alliance for Vaccines and Immunisation) with the World Bank in a unique funding mechanism. To-date IFFIm has issued over $5bn of bonds in the international capital markets to fund immunisation.

In 2012 Edge established the Global Health Investment Fund ("GHIF"), a $108mm private equity style fund under the sponsorship of the Bill & Melinda Gates Foundation and Grand Challenges Canada, bringing together Governments funds, institutional investors, the pharma industry and individual investors in the first impact investment fund for Global Health, targeting infectious diseases and maternal health. Last year, Edge was appointed as the Chair of the UK's Global AMR Innovation Fund.

Whilst continuing to devote the majority of his time to Global Health, Edge has also been involved in the establishment of new mechanisms to fund climate change, catastrophe risk insurance and migrant communities in Jordan as a result of the Iraq/Syrian war.

Edge holds an MA in Biochemistry from Oxford University.

Lion's Head Global Partners
130 Buckingham Palace Road
Londen SW1W 9TR
United Kingdom

Tel.: +44 207 340 0404
Mail: edge@lhgp.com

GLOBAL AMR INNOVATION FUND

10TH BERLIN CONFERENCE ON LIFE SCIENCES

February 24, 2017

LION'S HEAD
global partners

O'NEILL REVIEW 2014-MAY 2016

- Commissioned by David Cameron in 2014
- "The cost in terms of lost global production between now and 2050 would be an enormous 100 trillion USD if we do not take action"
- **A ten point plan:**
- Public Awareness
- Antibiotics in Agriculture and Environment
- Surveillance
- Human Capital
- Global Innovation Fund
- Sanitation and Hygiene
- Vaccines and alternatives
- Rapid Diagnostics
- Drugs
- International Coalition for Action

2

LION'S HEAD

G7 – ISE SHIMA MAY 2016

- Health: We commit to take concrete actions for advancing global health as elaborated in the G7 Ise-Shima Vision for Global Health, highlighting that health is the foundation of economic prosperity and security. We commit to promote Universal Health Coverage (UHC) as well as endeavor to take leadership in reinforcing response to public health emergencies **and antimicrobial resistance (AMR) which could have serious impacts on our economies. We also emphasize promoting research and development (R&D) and innovation in these and other health areas.**

3

LION'S HEAD

G20 – HANGZHOU SEPTEMBER 2016

- 46: Antimicrobial resistance (AMR) poses a serious threat to public health, growth and global economic stability. We affirm the need to explore in an inclusive manner to fight antimicrobial resistance by developing evidence-based ways to prevent and mitigate resistance, **and unlock research and development into new and existing antimicrobials from a G20 value-added perspective**, and call on the WHO, FAO, OIE and OECD to collectively report back in 2017 on options to address this including the economic aspects.
- In this context, we will promote prudent use of antibiotics and take into consideration huge challenges of affordability and access of antimicrobials and their impact on public health. We strongly support the work of the WHO, FAO and the OIE and look forward to a successful high-level meeting on AMR during the UN General Assembly. We look forward to the discussion under the upcoming presidency for dealing with these issues.

4

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UNGA SEPTEMBER 2016

- On 21st September 2016 World Leaders discussed AMR at United Nations General Assembly, on the fourth time a Health issue has been placed on the UNGA agenda (previously HIV, Noncommunicable diseases and Ebola) and released a Political Declaration.
- **"Recognize that the keys to tackling antimicrobial resistance are:** the prevention and control of infections in humans and animals, including immunization, monitoring and surveillance of antimicrobial resistance; sanitation, safe and clean water and healthy environments; investing in strong health systems capable of providing universal health coverage; promoting access to existing and new quality safe, efficacious and affordable antimicrobial medicines based, where available, on diagnostic tests; sustained research and development for new antimicrobial and alternative medicines; rapid diagnostic tests, vaccines and other important technologies, interventions and therapies; promoting affordable and accessible health care; and resolving the lack of investment in research and development, including through the provision of incentives to innovate and improve public health outcomes, particularly in the field of antibiotics;
- **"Mobilize adequate, predictable and sustained funding** and human and financial resources and investment through national, bilateral and multilateral channels to support the development and implementation of national action plans, research and development on existing and new antimicrobial medicines, diagnostics, vaccines and other technologies and to strengthen related infrastructure, including through engagement with multilateral development banks and traditional and voluntary innovative financing and investment mechanisms, based on priorities and local needs set by governments, and ensuring public return on investment"

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GAMRIF – GLOBAL AMR INNOVATION FUND

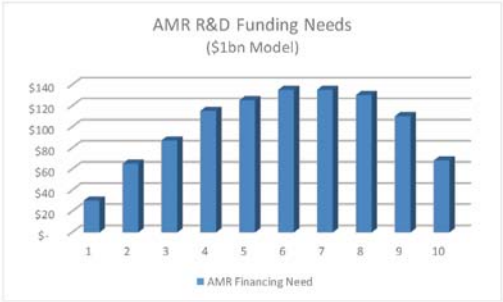
- GAMRIF is a new fund that the UK has committed to seed to fund innovative R&D in the field of AMR
- The Fund's initial capital base is £50 million from the United Kingdom, which it hopes to augment with additional capital from the UK's peers. The Bill & Melinda Gates Foundation has committed to provide $25 million.
- £10 million of the fund will be used to seed a matched investment programme with the Government of China
- In November 2016 an expert advisory board was established to advise the Government on what GAMRIF should prioritise. This Board will work over the course of 2017, with the objective of delivering a prioritised set of objectives to the Fund

6

LIONS HEAD

GAMRIF
WORKING HYPOTHESIS OF NEED

- There is an estimated immediate funding need of $2bn to accelerate R&D into the growing challenge of AMR. A number of initiatives already exist that contribute towards this nunmber
- Key focus on late stage programmes encouraging a "crowding in" the private sector
- Critically this is required as a long term funding stream over the next 10 years
- This requires a change in thinking from short term "projects" to a set of strategic initiatives



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LION'S HEAD global partners

GAMRIF
CHALLENGES TO BE OVERCOME

- Current funding landscape is growing…
- BARDA, CARB-X, IMI, Innovfin, Australian Biomedical Translation Fund, BMGF, National Science Programme, PDPs Wellcome Trust
- … but the sector is becoming increasingly fragmented
- AMR is an issue of a Global Public Good
  - "It is someone else's problem"
  - "It only impacts the old"
  - "It is caused by bad behavior in hospitals, so won't happen to me"
  - "Someone else will solve it"
- Apparent intractable conflicts
  - It requires less antibiotic use at a time when in large swaths of the world there is not enough antibiotic use
  - It requires a ONE health approach

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LION'S HEAD global partners

Christopher Egerton-Waburton, Lion's Head Global Partners, London, United Kingdom

PEOPLE FEAR A VIRAL PANDEMIC, BUT ARE LIVING WITH SEVERAL BACTERIAL ONES

- Few things strike more fear into the population than the concept of a large scale viral epidemic
- The costs of such events are in the hundreds of billions not tens of millions

- There is much less fear of a bacterial epidemic, but that is the reality we face and for individuals that reality is increasingly in their living room

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LIONS HEAD

AMR IN NUMBERS

- Estimated to be causing 2 million infections per year in each of US and Europe, with approximately 1% death rate (approximately 50% as a result of *clostridium difficile*)
- In developing countries the numbers are 10x, with TB, Klebsiella Pneumonia, E.coli and Gonorrhoea dominating
- New drugs are emerging, but the cost of development is so large because of the high failure rate
- In TB, Delamanid and Sirturo are changing the landscape, but the value of a cure is severely underpriced
- Contrast with rare pediatric diseases in the US which have price tags of $200,000-300,000 per patient

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LIONS HEAD

WHAT IS THE CONSTRAINT?

- The science is really hard
- Big pharma have scaled back not for a perceived lack of financial return, but due to the continued failure
- "Success is serendipitous"
- But the biotech industry is taking AMR seriously – 50 members of the BEAM Alliance, with similar enthusiasm in the USA
- Progress by WHO on stewardship will yield tangible results
- Academic research model is working well with increased allocations to scientific R&D
- However we fear that there is more focus on the new, than finishing what is already in the pipeline

11

LION'S HEAD

GAMRIF VISION

- A committed multi-donor capital pool with a 10 year vision
- One or more specialist allocation/investment groups to form development partnerships with private sector spin-outs or academic units
- A hub & spoke model, leveraging specialist skills globally via regional centres or programmes, but linked formerly to a common platform, critically to strengthen collaboration vs. tendencies to a unilateral approach

In addition GAMRIF supports:

- Greater regulatory oversight and control granted to WHO
- Leverage global fora such as UNGA and G7/20

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LION'S HEAD

Notes

Stimulating innovation: Novel approches to incentivising antibacterial R&D

David Findlay

Deputy Coordinator Drive-AB

GlaxoSmithKline, Brentford

After graduating with a BSc in neuropsychology, David entered the pharmaceutical industry, holding UK sales and marketing positions in J&J (Janssen-Cilag) before gaining his MBA majoring in business strategy. After the MBA, he worked in Cilag's EU regional office in Zug, Switzerland delivering marketing and training to Eastern Europe affiliates.

David then moved to Glaxo's UK operation in a marketing role progressing through a number of commercial positions, before developing his global experience in the US leading global commercial strategy for the antibacterial portfolio.

Returning to the UK, David then focussed on antibacterial strategy for pipeline antibiotics, becoming involved in the evolving landscape for new economic models to incentivise antibacterial R&D. Currently, David is GSK's representative on the IMI project, DRIVE-AB. David co-leads Work Package 2 (WP2) responsible for developing new commercial models for incentivising antibacterial R&D.

GlaxoSmithKline
GSK House
Brentford
Middlesex
TW8 9 GS
United Kingdom

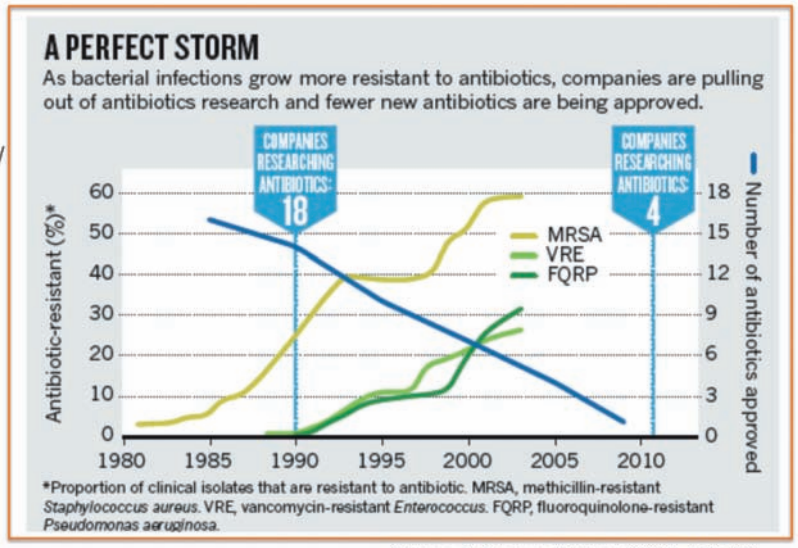
Tel.: +44 20 8047 5000
Mail: james.d.findlay@gsk.com

A perfect storm – as resistance increases, the availability of innovative antibacterials decreases

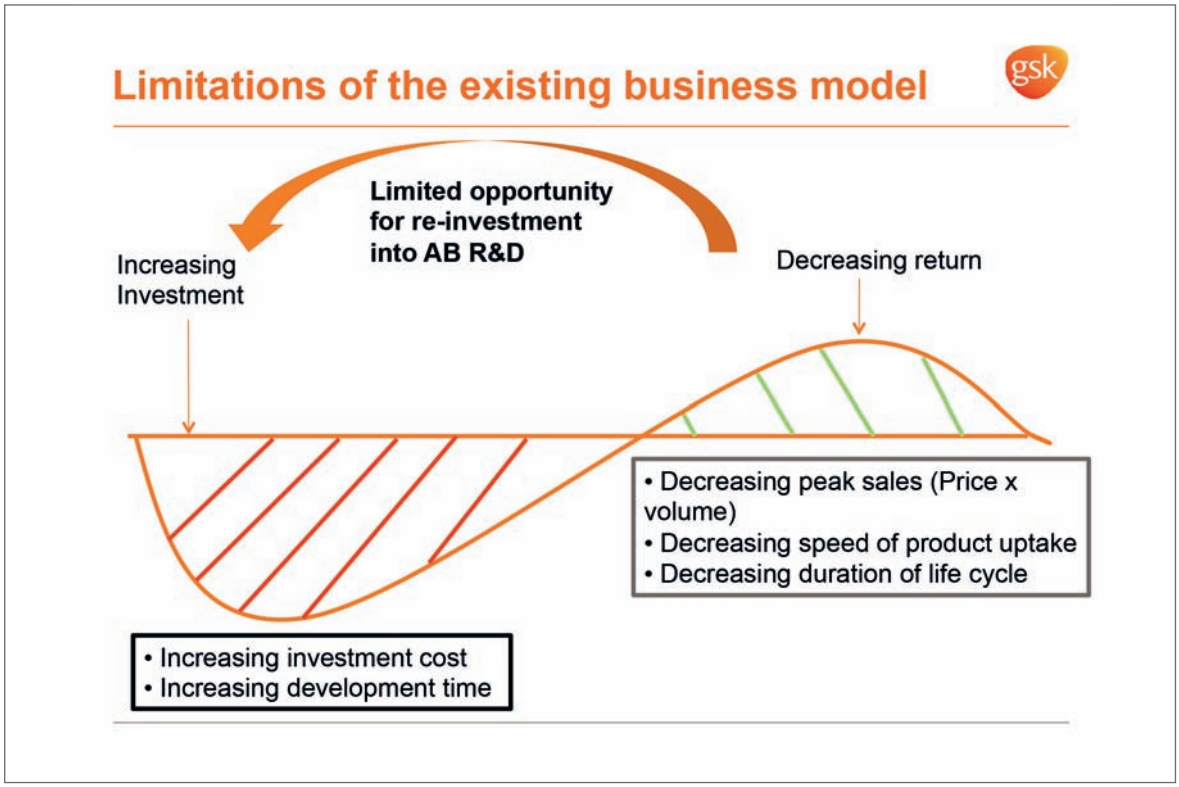
gsk

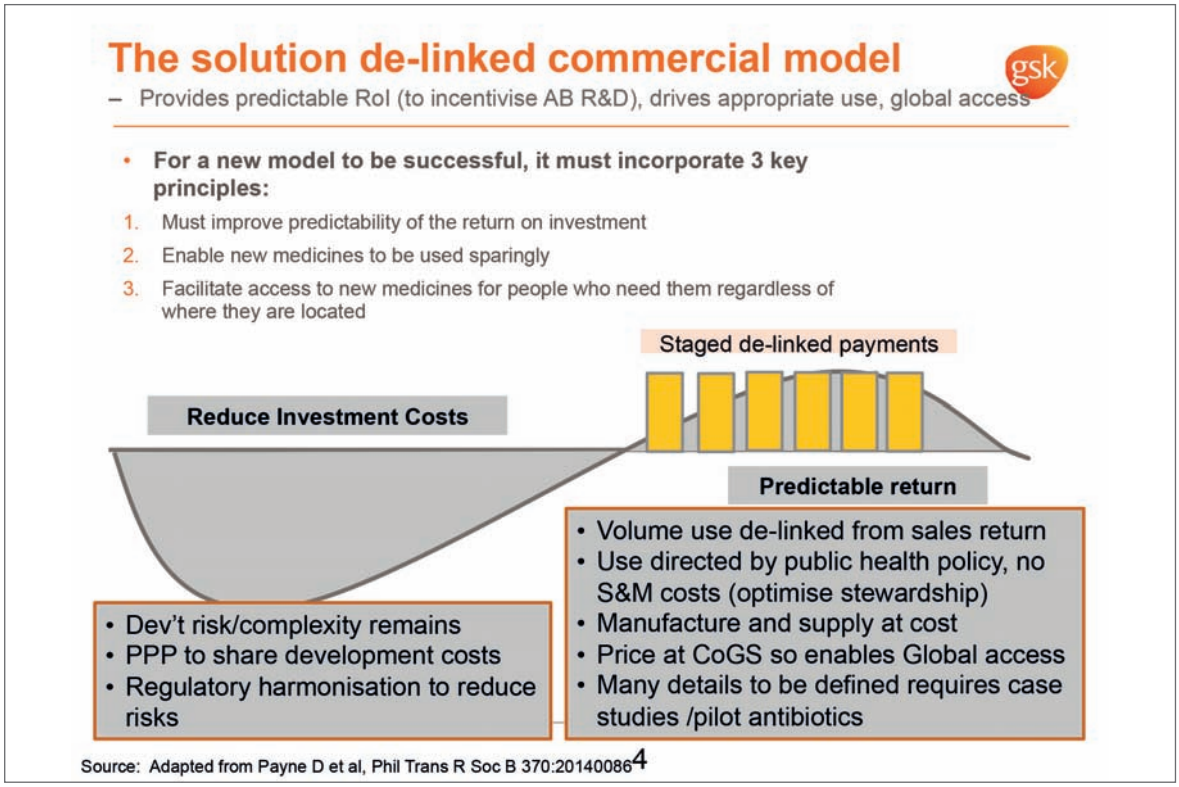
Challenges:

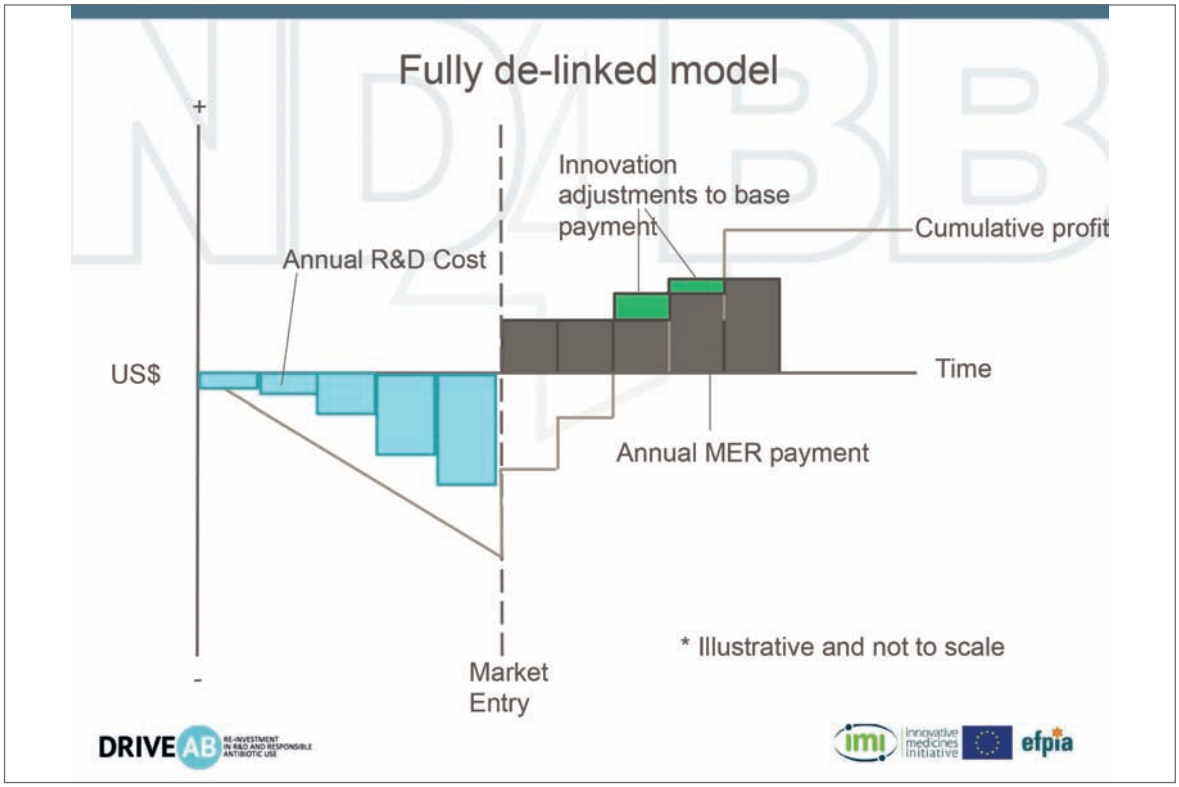
1. Scientific challenge
2. Clinical trials/ regulatory
3. Low return on investment

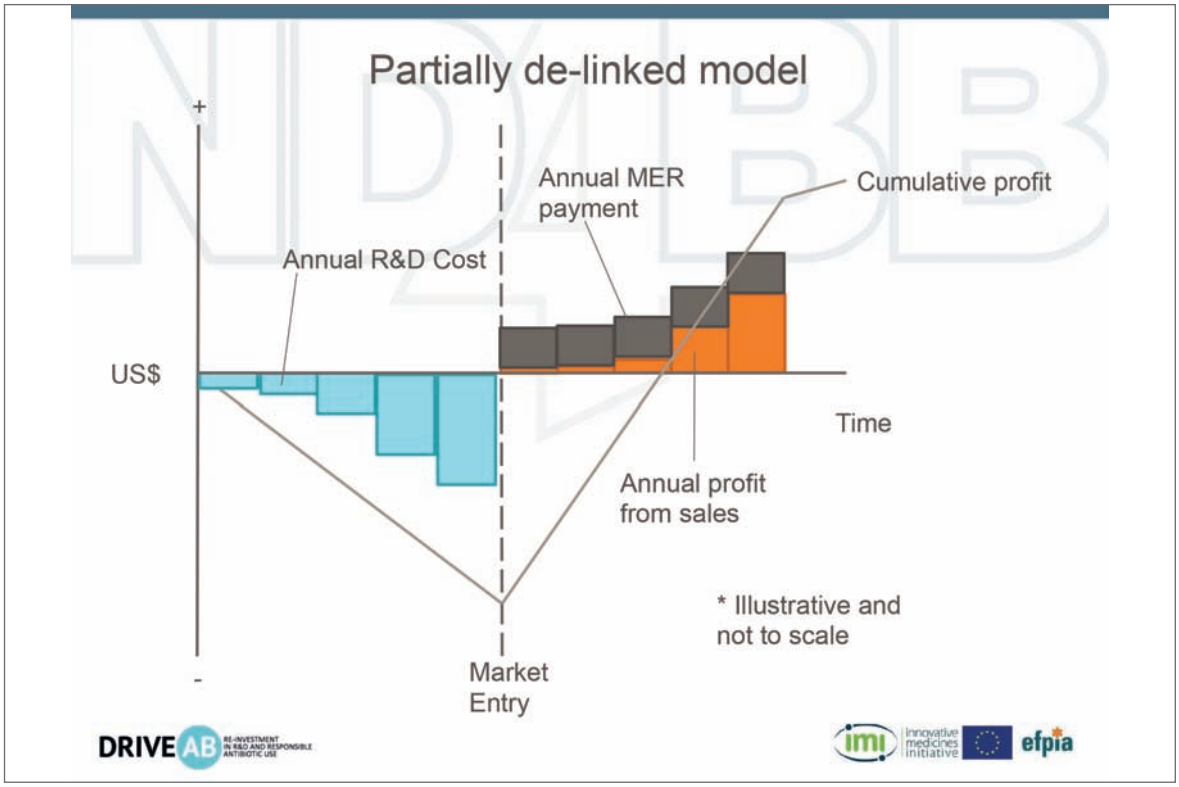


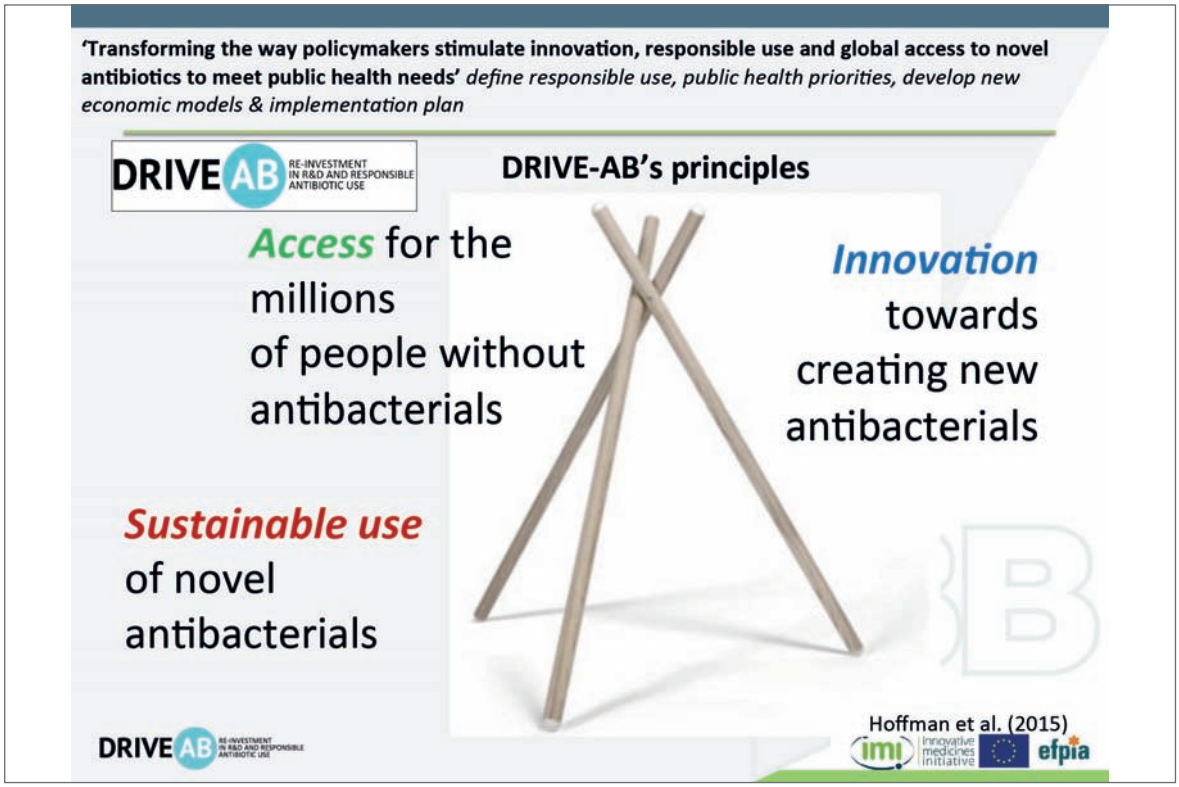
Shlaes & Cooper, Nature (2011) **472;** 32


Limitations of the existing business model
gsk
Limited opportunity for re-investment into AB R&D
Increasing Investment
Decreasing return
• Decreasing peak sales (Price x volume)
• Decreasing speed of product uptake
• Decreasing duration of life cycle
• Increasing investment cost
• Increasing development time


The solution de-linked commercial model
gsk
– Provides predictable RoI (to incentivise AB R&D), drives appropriate use, global access
• For a new model to be successful, it must incorporate 3 key principles:
1. Must improve predictability of the return on investment
2. Enable new medicines to be used sparingly
3. Facilitate access to new medicines for people who need them regardless of where they are located
Staged de-linked payments
Reduce Investment Costs
Predictable return
• Volume use de-linked from sales return
• Use directed by public health policy, no S&M costs (optimise stewardship)
• Manufacture and supply at cost
• Price at CoGS so enables Global access
• Many details to be defined requires case studies /pilot antibiotics
• Dev't risk/complexity remains
• PPP to share development costs
• Regulatory harmonisation to reduce risks
Source: Adapted from Payne D et al, Phil Trans R Soc B 370:20140086
4


Fully de-linked model
+
-
US$
Time
Innovation adjustments to base payment
Cumulative profit
Annual R&D Cost
Annual MER payment
Market Entry
* Illustrative and not to scale
DRIVE AB
imi
innovative medicines initiative
efpia


Partially de-linked model
+
-
US$
Time
Annual MER payment
Cumulative profit
Annual R&D Cost
Annual profit from sales
Market Entry
* Illustrative and not to scale
DRIVE AB
imi
innovative medicines initiative
efpia



DRIVE-AB's shortlist of incentives

Incentive/Model	Type	Type of innovation stimulated	De-linkage
Grants	Push	Early phase research	n/a
Non-Profit Antibiotic Developer	Push	Incremental innovation and development with a higher risk profile	n/a
Diagnosis Confirmation Model	Pull	Greater diversity of broad and narrow-spectrum antibiotics with significant improvements	No
Insurance Licenses	Pull	Rarely used, emergency antibiotics	Yes
Market Entry Rewards	Pull	Most pressing public health threats	Yes

UK initiatives to Address AMR reflect a positive approach to 'fixing' the 'broken' commercial model

- Professor Dame Sally Davies, England's CMO is at the forefront of UK and International initiatives to address AMR
- UK's AMR Review recommendations are internationally respected and referenced: increased funding recommended
- UK funders contributing to CARB-X 'push' funding
- ABPI and DH/NICE working to deliver a de-linked pilot to test the model of 'pull' incentives
- AMR industry policy: Davos Declaration and IFPMA roadmap

GSK – UK Footprint

Operating in the UK for over 300 years

c16,000 Employees (2016)

£5.3bn Total contribution to UK GDP (2013)

18 sites within the UK comprising:
- 9 Manufacturing
- 6 R&D
- 4 Offices
- 1 Global HQ

Over £700m investment in R&D (2015), 25% of our global investment

Committed to reducing the environmental impact of operations along our entire supply chain

31% reduction in CO2 emissions
28% reduction in total energy used
80 fold increase in renewable energy
(2010)

Putting the patient first

UK/COM/0117/15(1)
Date of preparation: September 2016

Funding the research and development of novel antibiotics: The perspective of a start-up company

Nicholas Benedict

Co-Founder & CEO

Allecra Therapeutics, Weil am Rhein

Nicholas Benedict is Co-founder & CEO of Allecra Therapeutics, a company dedicated to the development of novel treatments to combat drug-resistant bacterial infections.

Nicholas gained a BA (Hons) in Philosophy from King's College London University and an MBA from the University of Manchester, UK. Over his 25 years in the Pharma and Biotech industries Nicholas has a successful track record across the full spectrum of the Pharma/Biotech value chain, starting in finance in F. Hoffmann-La Roche before moving to marketing and sales followed by general management roles including responsibility for R&D. Positions included Global Head of Anti-infectives Business Unit at Novartis AG in Switzerland, pharmaceuticals Country Manager at Novartis UK, Chief Commercial Officer at Basilea Pharmaceutica, where he successfully co-led the company's follow-on offering raising over CHF320 million on the public equity markets, and CEO of Swiss start-up Lumavita AG.

Nicholas subsequently co-founded Allecra Therapeutics where he has led Series A and B financing rounds, and progressed the lead compound from pre-clinical into Phase 2 with fast-track designation from the FDA.

Nicholas lives in Basel, Switzerland and holds both British and Swiss nationalities.

Allecra Therapeutics GmbH
Im Kränzliacker 9
79576 Weil am Rhein
Germany

Tel.: +41 79 592 2005
Mail: nmb@allecra.com

Everyone Knows Something about the Problem

BBC NEWS

March 2013

Analysis: Antibiotic apocalypse

A terrible future could be on the horizon, a future which rips one of the greatest tools of medicine out of the hands of doctors

nature

July 2014

Antibiotic resistance: The last resort

Health officials are watching in horror as bacteria become resistant to powerful carbapenem antibiotics — one of the last drugs on the shelf.

Public Health England

December 2015

25,000 people die each year as a result of hospital infections caused by **5 key resistant bacteria**

US Center for Disease Control (CDC) Report 2013

Estimated minimum number of illnesses and deaths caused by antibiotic resistance*:

At least **2,049,442** illnesses, **23,000** deaths

The Washington Post

May 2016

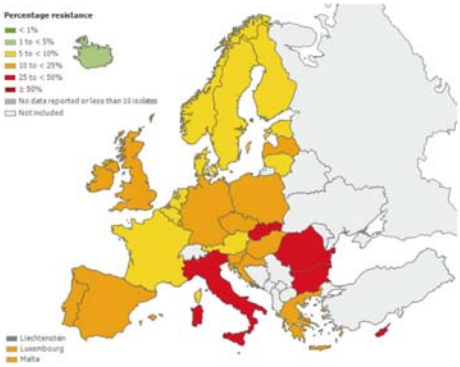
The superbug that doctors have been dreading just reached the U.S.

2

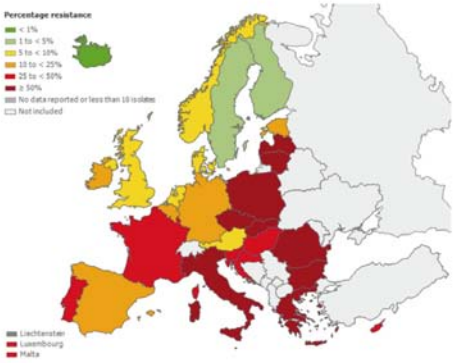
Gram-negative Resistance to Antibiotics is Widespread

Proportion of invasive *Escherichia coli* and *Klebsiella pneumoniae* isolates resistant to 3rd-generation cephalosporins (2014)

Escherichia coli



Klebsiella pneumoniae



From the ECDC website (http://ecdc.europa.eu/en/healthtopics/antimicrobial-resistance-and-consumption/antimicrobial_resistance/database/Pages/map_reports.aspx)

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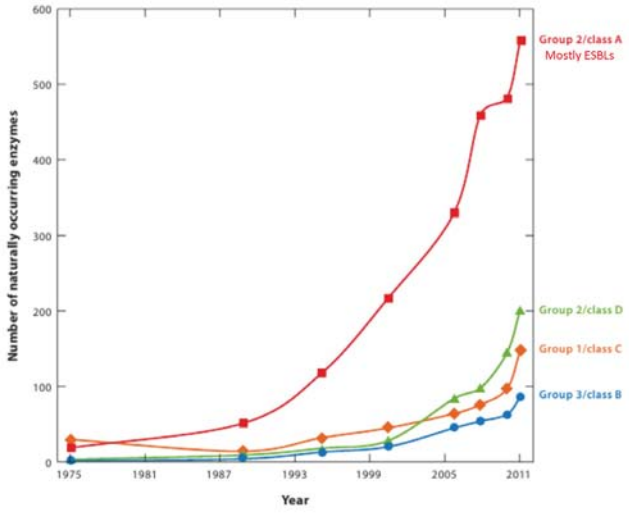
Gram-negative Resistance is Growing Exponentially

Increase in number of unique β-lactamases, according to molecular class



Source: Bush & Fisher, Annu. Rev. Microbiol. 65: 455-478 (2011)

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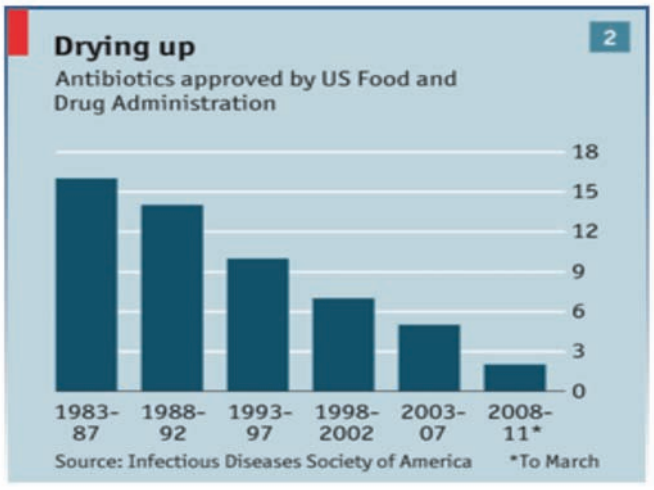
Industry Pipeline of Antibiotics in Significant Decline



Source: IDSA from Economist, March 2011

5

The Area Supports Some Blockbusters

CUBIST PHARMACEUTICALS

NOVARTIS

Once-A-Day CUBICIN® (daptomycin for injection)

- Launched in 2003
- Worldwide sales 2014: US$1.1bn *

Pfizer

IV/Oral ZYVOX® (linezolid)

- Launched in 2000
- Worldwide sales 2014: US$ 1.5bn*

* Sources: public company accounts

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No Antibiotics in Best Selling Drugs of All Time

Pharma's Biggest Blockbusters				
Brand name	**Generic name**	**Peak year sales**	**Peak sales ($m)**	**Product type**
Lipitor	atorvastatin	2006	13696	Small molecule
Plavix	clopidogrel	2011	9927	Small molecule
Humira	adalimumab	2012	9265	Biologic
Remicade	infliximab	2012	8215	Biologic
Seretide	fluticasone/salmeterol	2011	8117	Small molecule
Enbrel	etanercept	2012	7973	Biologic
Abilify	aripiprazole	2012	7597	Small molecule
Rituxan	rituximab	2012	7154	Biologic
Crestor	rosuvastatin	2011	6622	Small molecule
Lantus	insulin glargine	2012	6378	Biologic
Herceptin	trastuzumab	2012	6281	Biologic
Losec	omeprazole	2000	6260	Small molecule
Avastin	bevacizumab	2010	6216	Biologic
Diovan	valsartan	2010	6053	Small molecule
Seroquel	quetiapine	2011	5828	Small molecule
Singulair	montelukast	2011	5479	Small molecule
Zocor	simvastatin	2002	5445	Small molecule
Nexium	esomeprazole	2007	5216	Small molecule
Zyprexa	olanzapine	2010	5026	Small molecule

Source: Company reported data

7

Status June 2013. www.firstwordpharma.com

Avycaz® & Zerbaxa® US pricing

Zerbaxa® 1.5g (1 g ceftolozane + 0.5 g tazobactam) price per vial: (effective 12/22/2014)

- WAC: $83
- AWP: $99.6

Zerbaxa® recommended dosage and daily price by indication

Infection	Dosage	Frequency	Infusion time (hours)	Recommended duration of total treatment	Price per day for patients with normal renal function	
					WAC ($)	AWP ($)
cIAI (in combination with metronidazole 0,5 g iv q 8 h)	1.5 g (1 g+ 0.5 g)	Every 8 hours	1	4 to 14 days	249	298.8
cUTI (including pyelonephritis)	1.5 g (1 g+ 0.5 g)	Every 8 hours	1	7 days	249	298.8

Avycaz® 2.5 g (2 g ceftazidime + 0.5 g avibactam) price per vial: (effective 04/02/2015)

- WAC*: $285
- AWP**: $342

Avycaz® recommended dosage and daily price by indication

Infection	Dosage	Frequency	Infusion time (hours)	Recommended duration of total treatment	Price per day for patients with normal renal function	
					WAC ($)	AWP ($)
cIAI (in combination with metronidazole)	2.5 g (2 g+ 0.5 g)	Every 8 hours	2	5 to 14 days	855	1'026
cUTI (including pyelonephritis)	2.5 g (2 g+ 0.5 g)	Every 8 hours	2	7 to 14 days	855	1'026

*WAC = Wholesale Acquisition Price. Effectively, Ex-factory price
**AWP = Average Wholesale Price. Effectively, price to payer

8

Constant Stream of New Antibiotics Is Integral to Solving The Problem

- Improved hospital hygene
- Antibiotic Stewardship
- Novel Antibiotics

9

Alternative Approaches to Fixing the Problem

The Commercial Model is Broken

- R&D into novel antibiotics is inadequately funded
  - Because commercial model provides inadequate ROI
- Novel antibiotics should be reserved for appropriate use
  - Slow uptake is a goal of antibiotic stewardship
- Public funding for commercially unviable products
  - Extreme proposal for Public Pharma Co.

The Commercial Model Needs Help

- Aim to mobilise private capital
- Commercial funding for antibiotic R&D is attracted by improved risk/return
  - Size of investment
  - Time to fruition
  - Exit consideration
  - Associated risk
- US 2012 "GAIN" Act & 2016 "21st Century Cures" Act
  - Expedited pathway to approval
    - less capital required, less time to fruition
  - Special consultations with Agency
    - reduces risk of programme
  - 5 years additional market exclusivity
    - Increases potential returns
- "Push" & "Pull" incentives

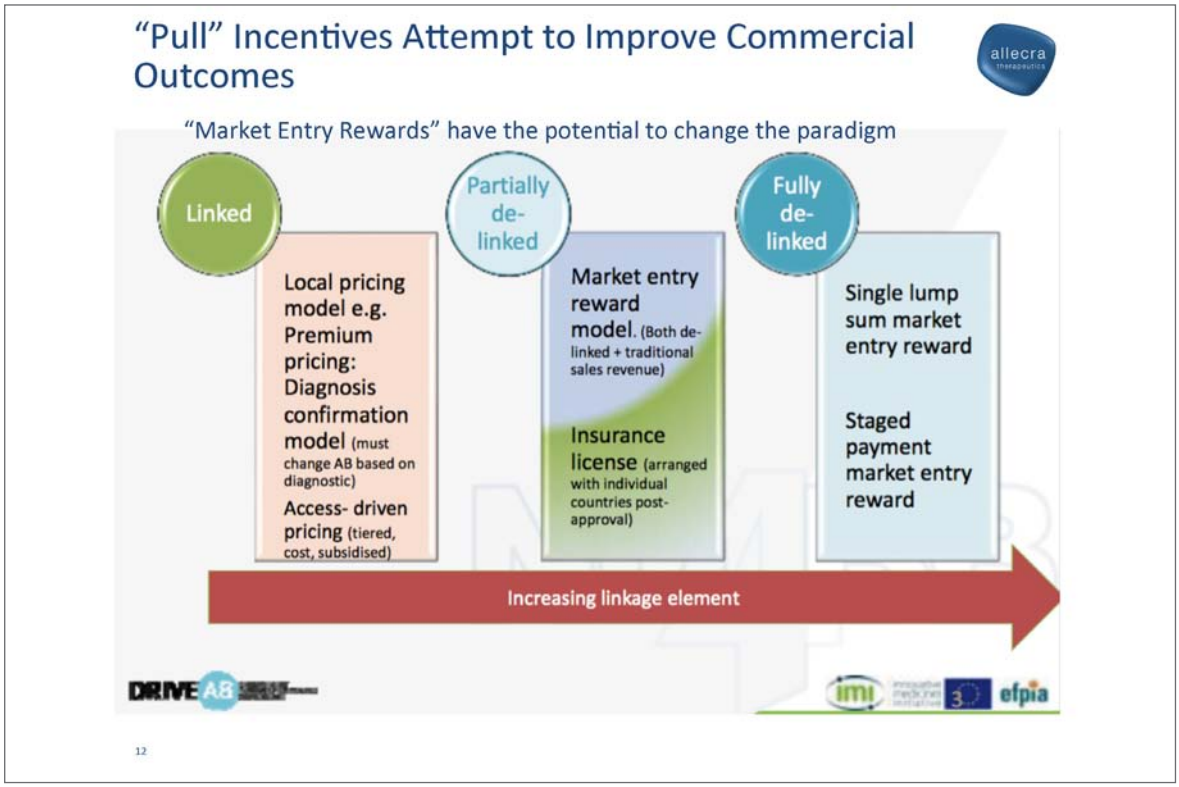
10

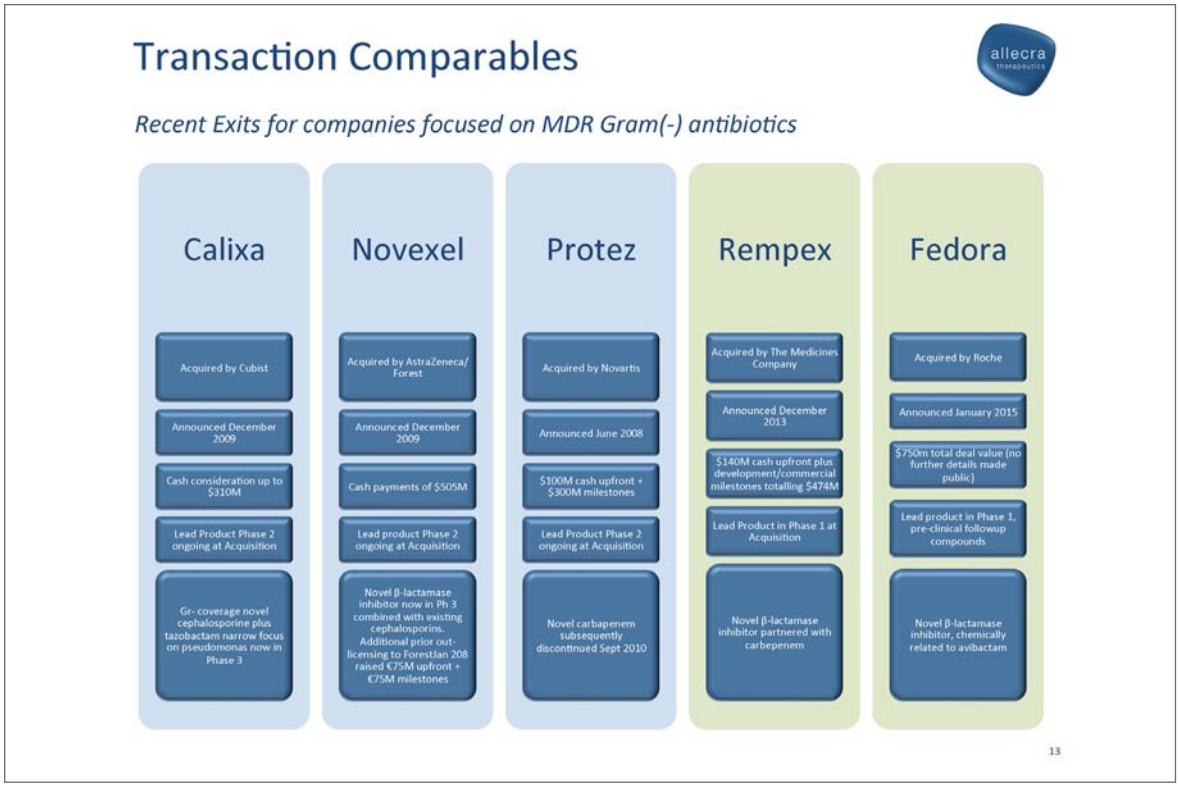
"Push" Incentives Make More Capital Available

- *Supporting open access to research* – providing and sharing scientific databases and molecule libraries[12,13]
- *Grants for scientific personnel* – funding training and development of personnel specializing in R&D of antibiotics[12,13]
- *Direct funding* – subsidies offered to organizations for the R&D of novel antibiotics[12,13]
- *Conditional grants* – subsidies offered to organizations for the R&D of novel antibiotics that are specifically tied to conservation conditions in the event the antibiotic is successfully launched[10]
- *Funding translational research* – funding for facilitating cooperation and interaction throughout the entire supply chain including research, commercial development, and clinical application[12,13]
- *Tax incentives* - tax credits, allowances, or deferrals that are tied to early R&D and reduce a developer's current tax liability[12,13]
- *Refundable tax credits* – tax credits that can be redeemed for cash instead of reducing current tax liability[39]
- *Product development partnerships (PDPs)* – collaborative agreements to share development risk and reward between a public or quasi-public organization and one or more private developers (e.g. IMI and the ND4BB Initiative)[12,13,32,40]

Source: *IMI, Innovative Medicines Initiative; ND4BB, New Drugs for Bad Bugs; R&D, research and development 2013.*

11


"Pull" Incentives Attempt to Improve Commercial Outcomes
allecra therapeutics
"Market Entry Rewards" have the potential to change the paradigm
Linked
Partially de-linked
Fully de-linked
Local pricing model e.g. Premium pricing: Diagnosis confirmation model (must change AB based on diagnostic)
Access- driven pricing (tiered, cost, subsidised)
Market entry reward model. (Both de-linked + traditional sales revenue)
Insurance license (arranged with individual countries post-approval)
Single lump sum market entry reward
Staged payment market entry reward
Increasing linkage element
DRIVE AB
imi
3
efpia
12


Transaction Comparables
allecra therapeutics
Recent Exits for companies focused on MDR Gram(-) antibiotics
Calixa
Acquired by Cubist
Announced December 2009
Cash consideration up to $310M
Lead Product Phase 2 ongoing at Acquisition
Gr- coverage novel cephalosporine plus tazobactam narrow focus on pseudomonas now in Phase 3
Novexel
Acquired by AstraZeneca/ Forest
Announced December 2009
Cash payments of $505M
Lead product Phase 2 ongoing at Acquisition
Novel β-lactamase inhibitor now in Ph 3 combined with existing cephalosporins. Additional prior out-licensing to Forestlan 208 raised €75M upfront + €75M milestones
Protez
Acquired by Novartis
Announced June 2008
$100M cash upfront + $300M milestones
Lead Product Phase 2 ongoing at Acquisition
Novel carbapenem subsequently discontinued Sept 2010
Rempex
Acquired by The Medicines Company
Announced December 2013
$140M cash upfront plus development/commercial milestones totalling $474M
Lead Product in Phase 1 at Acquisition
Novel β-lactamase inhibitor partnered with carbepenem
Fedora
Acquired by Roche
Announced January 2015
$750m total deal value (no further details made public)
Lead product in Phase 1, pre-clinical followup compounds
Novel β-lactamase inhibitor, chemically related to avibactam
13

Notes

SESSION

Market access in the era of AMR – bringing ideas to the patients

Moderator: Peter West

Compulsory licenses – bliss or doom for pharma industry

Ute Kilger

Partner

BOEHMERT & BOEHMERT, Berlin

Ute Kilger is assisting pharmaceutical and biotechnology companies as well as academic institutes in all kinds of patent related issues concerning the obtaining and enforcement of property rights, due diligence, mergers and acquisitions, contract negotiations, and licensing agreements. Her counseling is driven by the understanding that a patent strategy has to add value to the company. She manages large patent portfolios in view of the business strategies as well as the cost-benefit analysis. She is involved in patent infringement processes where she is representing her clients in nullity suits up to the German Federal Supreme Court of Justice.

For more than ten years, she was active in the patent departments of large pharmaceutical companies. Ute Kilger gained expertise in US patent law when she spent several months abroad in an American patent law firm. In 2002, she joined the patent department of Schering AG, where she became the head of the department in 2004, being responsible for the global patenting in the area of molecular imaging. She is licensed as a German and European patent attorney.

Ute Kilger is a lecturer at the University of Potsdam, and for the SPARK educational program of the Charité-Universitätsmedizin Berlin. *Best Lawyers 2016* is counting her as one of the most important patent attorneys in the field of biotechnology in Germany. *Legal 500 Germany 2015* highlights her accomplishments related to license agreements. Since August 2009, she has been working as a partner of BOEHMERT & BOEHMERT.

Ute Kilger is a member GRUR, VPP, and LES. She is co-chair of the Global Series Committee of the Federal Circuit Bar Association (FCBA).

BOEHMERT & BOEHMERT
Kurfürstendamm 185
10707 Berlin
Germany

Tel.: +49 30 2360767 0
Mail: kilger@boehmert.de

Conflicting Interests

- The patentee has an interest in excluding others from the market in order to get return-on-investment from his blockbuster also for failed projects
  - A patent may provide such exclusion rights
- The public has an interest in obtaining the (blockbuster) medicament in sufficient quantities and/ or at a low price, in particular in developing countries

Patent-based Injunction

A granted patent may be enforced against third parties not having a license before ordinary courts

In normal (main) patent infringement procedures „automatically“ as a matter of Law (Section 139 German Patent Act (GPA))

- Immediately enforceable, against bond, after verdict in infringement procedure (irrespective of still pending opposition/invalidation procedure)

In fast injunction procedures: depending on balanced interests of patentee/defendant

German Patent Act (GPA) – Compulsory Use Permission

- Use order according to Sect. 13 German Patent Act (GPA)
  - In the interest of public welfare
- Compulsory license according to Sect. 24(1) GPA/Art. 31 TRIPS
  - If voluntary license not obtainable and if there is public interest
- Compulsory license for dependent patents (Sect. 24(2) GPA)
  - If important technical progress of significant economical importance
  - And if "counter"-license is granted

4 Dr. Ute Kilger – Patent Attorney BOEHMERT & BOEHMERT

Compulsory Licensing – Sect. 24(1) GPA

- Request only possible after patent grant
- To-be licensee must be able and willing to use compulsory license himself
- Only possible after refusal of reasonable voluntary (contractual) license
- Public interest necessary
  - Is presumed if use of the invention, compared with the interests of the patentee, is of higher common value

5 Dr. Ute Kilger – Patent Attorney BOEHMERT & BOEHMERT

Compulsory License – Prominent Examples

- In 2012 Indian courts granted a compulsory license to an Indian generic pharmaceutical company under Bayer's patent for its cancer drug Nexavar, determining that in essence Bayer's price for Nexavar was too high, in 2014 India's Supreme Court denied Bayer's final appeal

- In 2016, the German Patent Court granted a provisional compulsory license to a Shionogi patent allowing Merck to continue to market the HIV-drug Raltegravir, that is sold as Isentress® in Germany

6 Dr. Ute Kilger – Patent Attorney BOEHMERT & BOEHMERT

Bliss or Doom?

- Pharmaceutical companies fear that patent protection will be undermined if (generic) companies obtain a compulsory license for patent protected originator drugs, in particular block buster drugs
- However - what may be the alternative showed the Glivec case in India where the Indian Patent Office (confirmed by all higher courts) denied patent protection for a novel and surprisingly improved salt form of a cancer drug

➢ The undermining of patentability rules may even more undermine the patent system

7 Dr. Ute Kilger – Patent Attorney BOEHMERT & BOEHMERT

Intellectual property rights and their role in fostering creation and distribution of innovations

Prof. Dr. Heinz Goddar

Partner

BOEHMERT & BOEHMERT, Munich

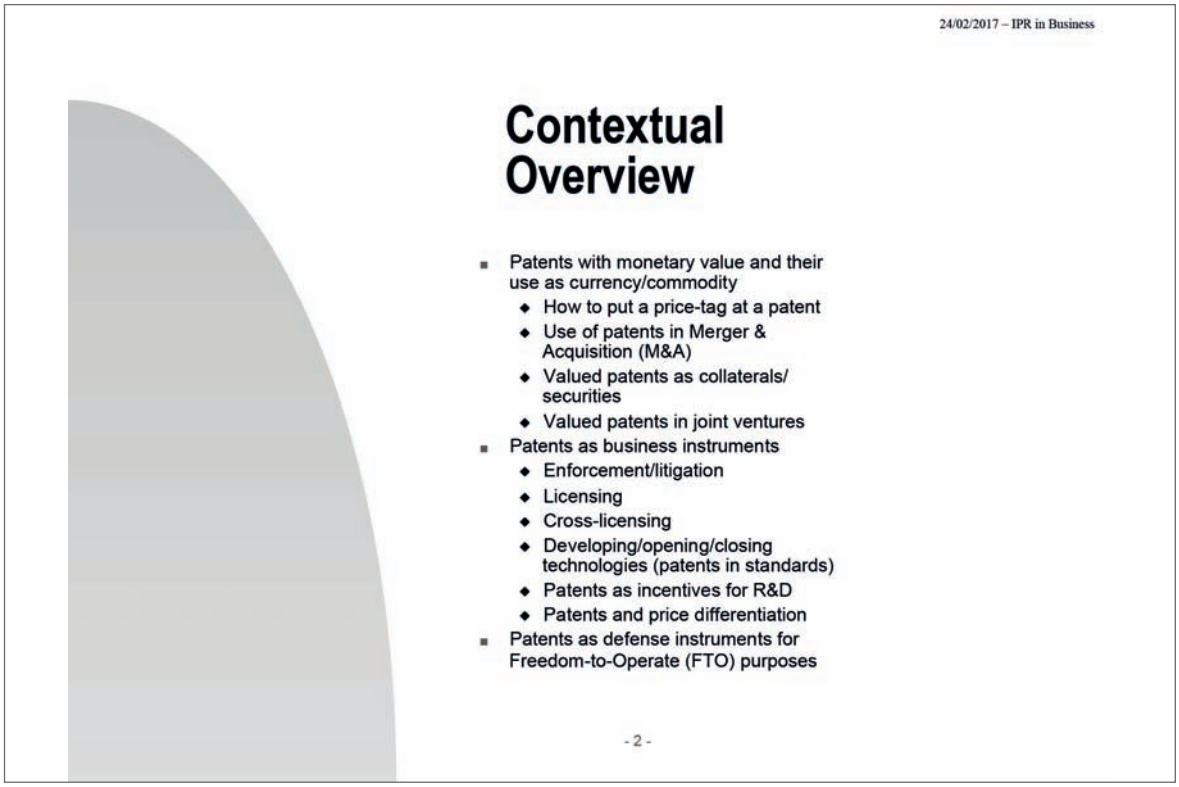
Heinz Goddar, Prof., Dr., a German Patent Attorney and European Patent and Trademark Attorney, is a partner of Boehmert & Boehmert, with his office at Munich, Germany. Technical background (as well as PhD degree) in physics, with a focus on polymer physics.

He teaches Patent and Licensing Law as an Honorary Professor at the University of Bremen, Germany, as a Lecturer at the Munich Intellectual Property Law Center (MIPLC), Munich, Germany, as a Visiting Professor at the University of Washington, Seattle, WA, U.S.A., and the National ChengChi University, Taipei, and as a Consultant Professor at the University of Huazhong, Wuhan, China. He is a member of the Advisory Board of the Tongji Global Intellectual Property Institute (TGIPI), Shanghai, China. Prof. Dr. Goddar is an Adjunct Professor and an Honorable Consultant in International Legal Services at the National Yunlin University of Science and Technology, Yunlin, Taiwan. He is also a Director at the Global Institute of Intellectual Property (GIIP), Delhi. He is a Past President of LES International and of LES Germany and has received the Gold Medal of LES International. In 2014 he has been inducted into the IP Hall of Fame.

BOEHMERT & BOEHMERT
22 Pettenkoferstrasse
80336 Munich
Germany

Tel.: +49-89-559680
Mail: goddar@boehmert.de


24/02/2017 – IPR in Business
Intellectual Property Rights and their Role in fostering Creation and Distribution of Innovations
Heinz Goddar
Boehmert & Boehmert
- 1 -


24/02/2017 – IPR in Business
Contextual Overview
Patents with monetary value and their use as currency/commodity
How to put a price-tag at a patent
Use of patents in Merger & Acquisition (M&A)
Valued patents as collaterals/ securities
Valued patents in joint ventures
Patents as business instruments
Enforcement/litigation
Licensing
Cross-licensing
Developing/opening/closing technologies (patents in standards)
Patents as incentives for R&D
Patents and price differentiation
Patents as defense instruments for Freedom-to-Operate (FTO) purposes
- 2 -

Commercial Use of Patents

- Protecting own business
  - keeping competitors away
- Excluding others from using own IP
- Securing Freedom-to-Operate (FTO)
- Paying for cross-licenses by own licenses
- Licensing out to obtaiin additional benefit

How to "Persuade" IPR Owners to Grant Licenses?

- By governments
  - public use order
  - Compulsory licensing
- By private enterprises
  - concentrating R&D on improvements of product desired to be licensed in
  - patenting improvements, particularly in main (home) market(s) of desired/target licensor
  - negotiating cross-license with licensor

Reasons for desired ("target") Licensor to Cross-License

- Obtaining freedom to act with regard to improvement patents held by "desiring" licensee
- Obtaining acess to improvement technology developed by desired licensee
  - particularly important in case of basic patent(s) of target licensing expiring soon (pharmaceuticals!)

Conclusions

- Patents increasingly used as currency surrogate
- Patents increasingly used for litigation purposes
- Patents as instruments for cross-licensing
- Patents as incentives
- Patents for price differentiation

From bench to clinic: developing new drugs for bad bugs on a European level

Prof. Anders Karlén

Professor in Computer-Aided Drug Design

Uppsala University

Anders Karlén received his Master of Science in Pharmacy degree from Uppsala University in 1984. He completed his Ph.D. degree with Uli Hacksell at Uppsala University in 1989. After a postdoctoral period at the School of Pharmacy, University of Lausanne, he joined the department of medicinal chemistry at Uppsala University in 1991 where he is currently Professor of Computer Aided Drug Design.

Anders is presently the overall medicinal chemistry project leader for drug discovery efforts currently directed at five different anti-bacterial targets at Uppsala University. Several of these projects have been run within EU framework 6 and 7 programmes. Since February 2014 he is the Leader of the Managing Entity and co-coordinator of the €85 million, 6 year, Innovative Medicines Initiative (IMI) project ENABLE (European Gram Negative Antibacterial Engine).

The ENABLE project, within IMI's New Drugs for Bad Bugs (ND4BB) programme, is working to advance the development of potential antibiotics against Gram-negative bacteria. The ultimate goal is to take at least one clinical candidate into a Phase I clinical study.

Uppsala University
Department of Medicinal Chemistry
Biomedical Centre, P.O. Box 574
751 23 Uppsala
Sweden

Tel.: +46 18 4714293
Mail: anders.karlen@orgfram.uu.se

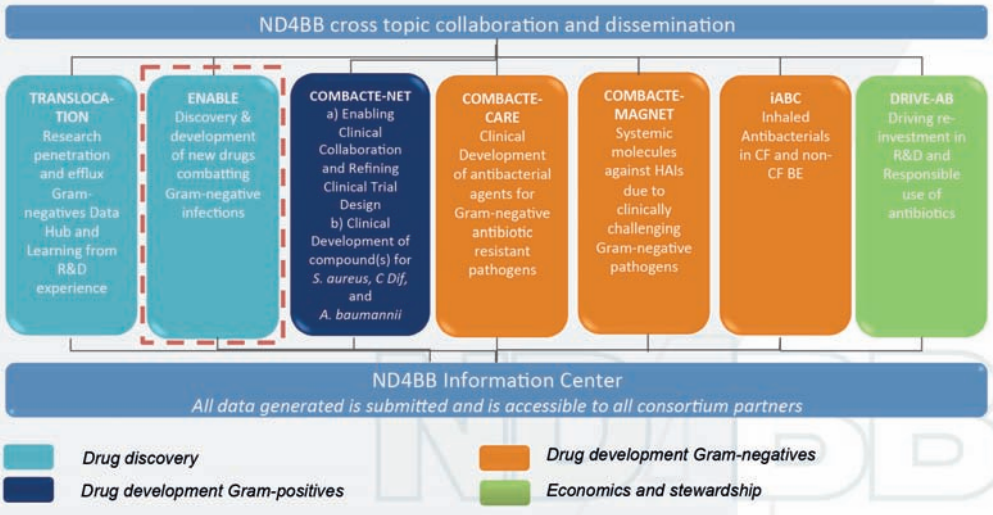
From bench to clinic: Developing new drugs for bad bugs on a European level

http://www.nd4bb-enable.eu/

Anders Karlén
Department of Medicinal Chemistry
Uppsala University

Total budget: > € 650 million

Overall architecture of ND4BB



ND4BB Programme as of 2017

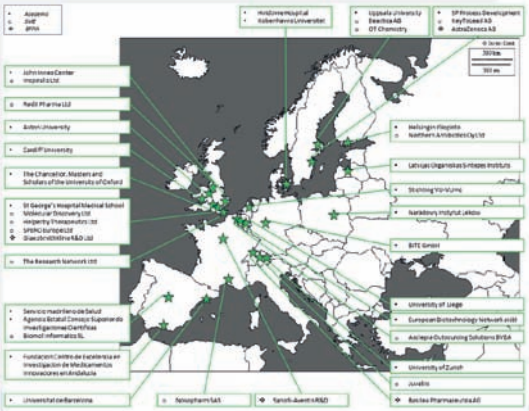
ENABLE: European Gram Negative Antibacterial Engine

Consortium with 39 partners:

Public partners (12 European countries)
Uppsala University managing entity
- *20 academic/institute/hospital organizations/non-profits*
- *15 SMEs*

Private partners (EFPIA)
GlaxoSmithKline (Pennsylvania, US)
EFPIA coordinator
- *Sanofi, AstraZeneca & Basilea*

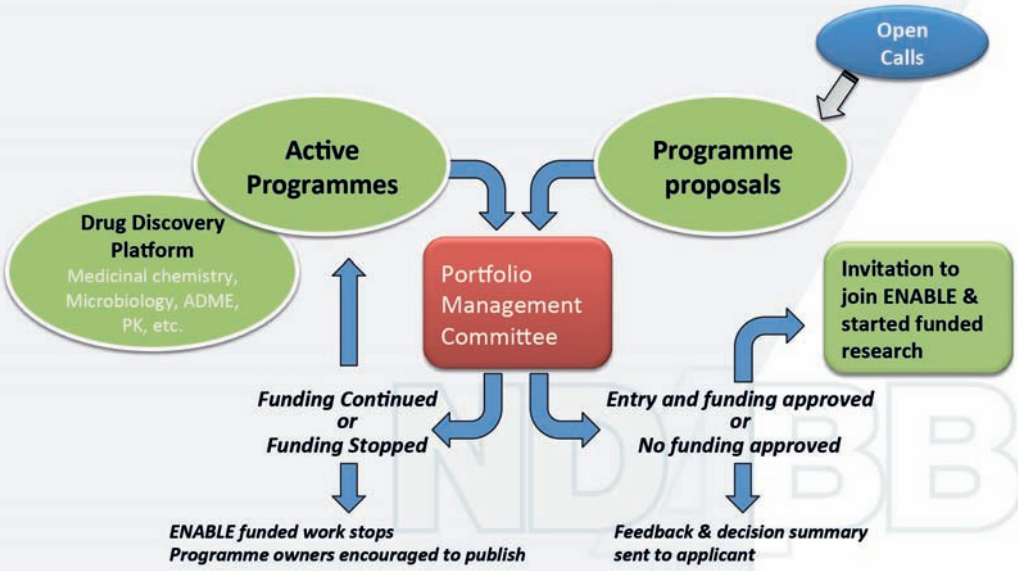
Launched Feb 2014, 6 year run time
- *Projected budget: €85 million*



Goals
- Create a collaborative drug discovery platform
- Kick start Gram-negative antibacterial discovery:
  - increase overall science base in the area
  - identify three Leads
  - identify two Development Candidates
  - progress at least one compound into Phase 1

3

Heart of ENABLE: PMC (funding) cycle



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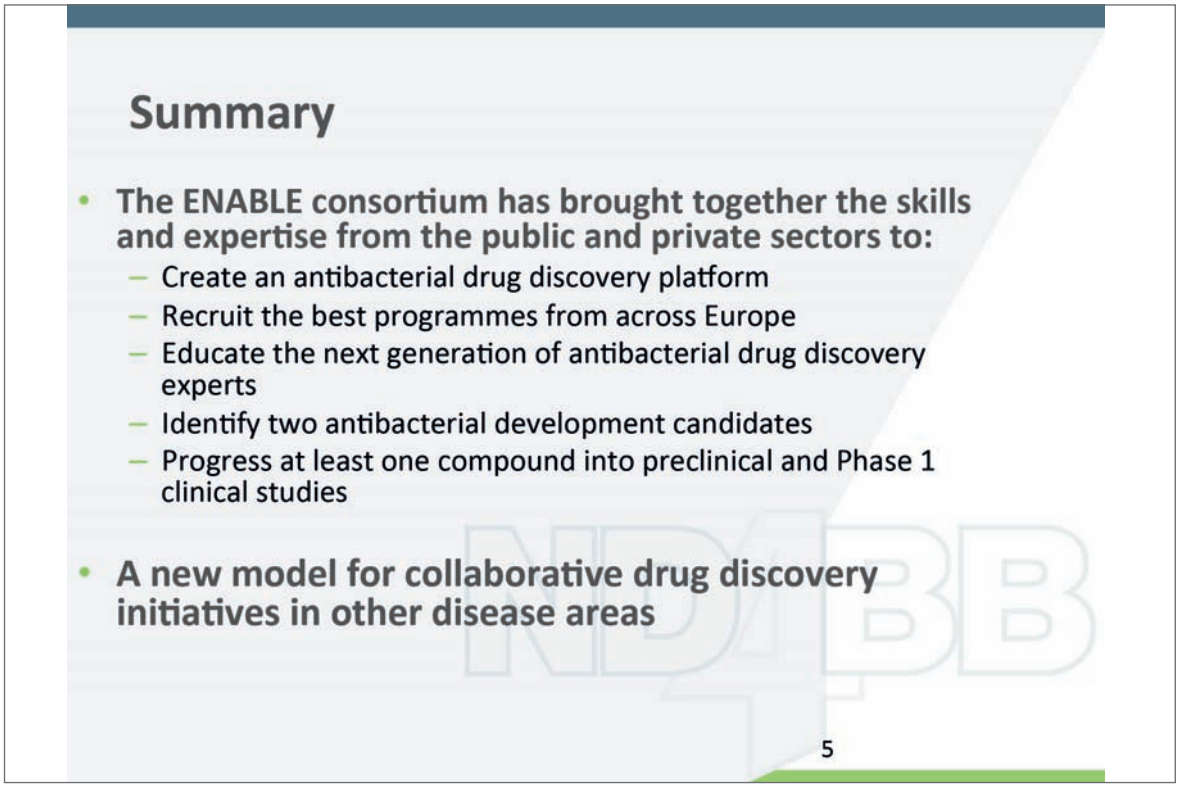

Summary
The ENABLE consortium has brought together the skills and expertise from the public and private sectors to:
Create an antibacterial drug discovery platform
Recruit the best programmes from across Europe
Educate the next generation of antibacterial drug discovery experts
Identify two antibacterial development candidates
Progress at least one compound into preclinical and Phase 1 clinical studies
A new model for collaborative drug discovery initiatives in other disease areas
5

The relevance of new methods for antimicrobial susceptibility testing

Prof. Hajo Grundmann

Member of EUCAST Subcommittee

University Medical Center Freiburg

Hajo Grundmann, born in 1955, studied Sinology, Nursing and Human Medicine at the Universities of Bochum and Freiburg, Germany. He specialised in Clinical Tropical Medicine, Medical Microbiology and Hygiene & Environmental Medicine and received his PhD at the University of Freiburg, Germany and an MSc in Epidemiology of Communicable Diseases at the London School of Hygiene. He worked clinically as a medical doctor at university hospitals in Freiburg, Berlin, and Nottingham and carried out extensive field studies in Taiwan, Venezuela and Tanzania. For eight years, he was the Project Leader of the European Antimicrobial Resistance Surveillance System (EARSS) funded by the European Commission and the Dutch Ministry of Health at the Dutch National Institute for Public Health and the Environment (RIVM).

Currently, he is the Head of Department for Infection Prevention and Hospital Epidemiology at the University Medical Centre in Freiburg, Germany. He also holds the Chair for Infectious Diseases Epidemiology at the University of Groningen. His major research interests are the molecular evolution, epidemiology, population dynamics and health impact of emerging antimicrobial resistance and health care associated infections. – Address: University Medical Centre Freiburg, Faculty of Medicine, University of Freiburg, Breisacherstr. 115b, 79106 Freiburg, Germany.

University Medical Center Freiburg
Infection Prevention and Hospital Hygiene
Breisacher Str. 115 B
79106 Freiburg
Germany

Tel.: +49 761 270-82750
Mail: hajo.grundmann@uniklinik-freiburg.de

The relevance of new methods for antimicrobial susceptibility testing.

Hajo Grundmann, University Medical Centre Freiburg, Germany

Topics

- Conventional antibiotic susceptibility testing
- Whole genome sequencing in antibiotic susceptibility testing
- Conclusions of an EUCAST subcommittee
- The role of WGS in AMR surveillance and drug development

Concluding comments 1

- Taken 50+ years for 'harmonization' of breakpoints
- An MIC reflects more than gene presence / absence
- Primary AST comparator for WGS-based prediction should be an ECOFF, wherever possible, i.e. categorisation of WT vs. non-WT
- Clinical breakpoints should be used as secondary comparators

3

Concluding comments 2

- The quantity and quality of evidence for AST phenotypic / genotypic concordance (or lack thereof) must improve.
  this is mainly due to poor use of ECOFFs in published literature.
- Must balance need for analysis to be more rigorous and 'standardised' (ISO accreditation etc.) with academic drivers for bioinformaticians to develop and improve their own tools
- Pragmatic to accept that algorithms can vary, but that they:
  should use the same centralised database of all known resistance genes / mutations (NCBI, ResFinder, CARD, ARIBA others)

Concluding comments 3

- WGS based charcterisation will likely replace conventional approaches to AMR surveillance for its power to
- provide a robust estimate of population diversity among clinically relevant isolates
- quantify the prevalence of individual resistance determinants
- describe geospatial dynamics
- inform trail design for drug developers

SESSION

SMEs to tackle AMR

Chair: Philippe Villain-Guillot

Nosopharm SAS

Philippe Villain-Guillot, Ph.D.

CEO & Co-Founder

Philippe Villain-Guillot, Ph.D., is President for Nosopharm, an anti-infective drug discovery biotech company he co-founded in February 2009. Prior to co-founding Nosopharm, he made his doctoral research in antibacterial medicinal chemistry under the supervision of Dr. Jean-Paul Leonetti, and received his Ph.D. at the University of Montpellier, France. He previously gained medicinal chemistry experience at Evotec (Oxford, UK), and natural products experience at CIATEJ (Guadalajara, Mexico). Philippe Villain-Guillot also holds a MSc from the Ecole Nationale Superieure de Chimie de Montpellier, and has been trained in innovation management at EMLYON Business School, Babson College, and Grenoble Ecole de Management. Philippe Villain-Guillot is the co-author of 10 scientific peer-reviewed articles and the co-inventor of 5 patent families in the field of antimicrobials.

Company Profile

Nosopharm is a biotech company dedicated to anti-infective drug discovery. Its mission is to discover and develop novel first-in-class antimicrobials addressing unmet medical needs, in partnerships with the biopharmaceutical companies. Nosopharm has designed and developed an innovative anti-infective drug discovery platform based on the medicinal mining of an original microbial bioresource: the bacterial genera Xenorhabdus and Photorhabdus. Exploiting this biotech platform, the company discovered and developed the Odilorhabdins, an entirely novel class of antibiotics for the treatment of multidrug-resistant hospital-acquired infections. Founded in 2009, Nosopharm is based in Nîmes, France, and has a staff of seven. The company raised €1.9m in private equity and received €1.8m in grants from DGA, Bpifrance, Region Languedoc-Roussillon, FEDER, and IMI. Nosopharm is a member of the BEAM Alliance, a group of Biopharmaceutical companies from Europe innovating in Anti-Microbial resistance research.

Nosopharm SAS
110 allee Charles Babbage
Innovation 2
30000 Nimes
Frances

Contact:
Philippe Villain-Guillot, CEO
t: +33 466 265 321
m: p.villainguillot@
nosopharm.com
www.nosopharm.com

Madam Therapeutics BV

Madam Therapeutics BV
Amstelkade 39A
3652 ME Woerdense Verlaat
The Netherlands

Contact:
Leonie de Best, CBO
t: +31 6 10961454
m: leonie.debest@
madam-therapeutics.com
www.madam-therapeutics.com

Leonie de Best

CBO

Leonie de Best is Chief Business Officer at Madam Therapeutics. She has a background in Analytical Chemistry and has 19 years of extensive management experience in biotech/life science industry, of which 5 years at senior executive level (COO). Leonie has a broad experience in the management of business processes in the field of (in vitro) diagnostic assay and pharmaceutical product development from research stage until market registrations. She loves to support young life science organizations like Madam Therapeutics to bring valuable and high quality health care solutions to patients.

Company Profile

Madam Therapeutics is an end of “pre-clinical stage” company that develops novel therapies to fight antimicrobial resistance (AMR). Madam Therapeutics has exclusively licenced-in IP from the Leiden University Medical Centre for a family of SAAPs (Synthetic Anti-Microbial and Anti-Biofilm Peptides) of which the lead peptide P148 is currently being developed for future clinical use. The company was founded in 2011, and has funded the pre-clinical work via own investments, grants and donations (€8.3M).

The peptides have a different mechanism of action compared to traditional antibiotics. The pre-clinical studies have shown that the product is well tolerated and very effective. They are active against gram+ as well as gram- (incl. multi-resistant) bacteria and they are intrinsically very robust against resistance formation.

Madam Therapeutics currently focusses on the development of a gel for topical application of P148, which would allow a relatively short time to market, for:

- Prevention and treatment of chronic wounds infections, including diabetic foot ulcers
- Treatment of infections in Burns
- Treatment of MRSA nasal carriers

Madam Therapeutics is now pursuing a series A financing round for the clinical proof of concept studies phase I/IIa, with the intention to out-licence and co-develop the products with larger pharmaceutical companies after that. We aim to raise €7,5M of which €4,3M through Equity investment and €3,2M through “Innovation Credit” by the Dutch Government.

Phico Therapeutics Ltd

Dr. Nicola Thompson

CBO

Dr Nicki Thompson is Chief Business Officer for Phico Therapeutics. She has over 20 years' experience in the Pharma and Biotechnology industries. She was previously at F. Hoffmann-La Roche Ltd, where she held the position of VP and Global Head of External Drug Discovery. In this role, Nicki built Roche's external discovery team and pipeline, leveraging innovative partnership models with Biotech and entrepreneurs. Prior to this, Nicki was Senior Director, Business Development for GSK's Centre of Excellence for External Drug Discovery (Ceedd), responsible for search and evaluation strategy and deal execution. In addition to her Pharma roles, Nicki has prior experience serving on Biotech executive management teams. As Head of Drug Discovery for Syntaxin Ltd., she shaped Syntaxin's discovery team and portfolio. Before her move to Syntaxin, Nicki was Allergic Mechanisms Head for GSK's respiratory therapy area. Nicki holds a PhD in Cell Biology from the Laboratory of Molecular Cell Biology (University College London).

Company Profile

Phico Therapeutics is a biotechnology company developing a novel platform technology which it believes could form the basis for a new generation of antibiotics to overcome antibacterial resistance. The company, founded in Cambridge by Dr Heather Fairhead, is built around its proprietary SASPject™ platform, which utilises small acid-soluble spore proteins (SASPs) that act as antibiotics by inactivating all bacterial DNA in a way that bacteria cannot evade, and could potentially prevent the spread of existing antibiotic resistance genes. Phico's lead program PT3.9, targeting P. aeruginosa is expected to enter Phase 1 in 2017.

Phico Therapeutics Ltd
Babraham Research Campus
Babraham,
Cambridge CB22 3AT
United Kingdom

Contact:
Dr. Nicola Thompson, CBO
t: +44 1223 496755
m: nt@phicotx.co.uk
www.phicotx.co.uk

Antabio SAS

Antabio SAS
Biostep
436 Rue Pierre et Marie Curie
31670 Labège
France

Contact:
Marc Lemonnier, CEO
t: +335 31 47 18 57
m: marc.lemonnier@
antabio.com
www.antabio.com

Marc Lemonnier, Ph.D.

CEO

Marc is the CEO and co-founder of ANTABIO and a member of the Board of the European Alliance of Biopharma companies combating Anti-Microbial resistance (BEAM Alliance). A molecular microbiologist by training, Marc has held several research positions in academia internationally and authored numerous peer-reviewed articles in the area of bacterial virulence and drug resistance. Under Marc's leadership, Antabio has attracted low double-digit million funding so far and received several awards including BIOVISION (2016) and two Seeding Drug Discovery Awards from the Wellcome Trust (2013 and 2015).

Company Profile

ANTABIO is a private biopharmaceutical company dedicated to the discovery and development of game-changing treatments for life-threatening and drug-resistant bacterial infections. Antabio has an experienced international antibacterial team, with specific expertise in the discovery and development of inhibitors of clinically-relevant bacterial metallo-enzymes (such as the NDM-1 metallo beta-lactamase). ANTABIO has developed a rich portfolio of first-in-class programs targeting high unmet needs in the antibacterial space.

In 2013 ANTABIO received a €4.7 Million Wellcome Trust Seeding Drug Discovery Award to fund the development of a novel, safe and efficacious inhibitor of bacterial metallo ß-lactamases up to preclinical candidate nomination. In 2015, ANTABIO received a second Wellcome Trust Seeding Drug Discovery Award (€4.0 Million) to support the development of novel small molecule drugs for the treatment of chronic Pseudomonas infections in Cystic Fibrosis (CF) patients. In addition, ANTABIO has established an industrial discovery engine supported by Bpifrance (the French public investment bank) which is dedicated to the discovery, evaluation and development of new combination and/or adjunctive antibiotic therapies

Morphochem AG

Dr. Thomas Kapsner

CEO

Thomas Kapsner has been serving as CEO of Morphochem AG, a 100% subsidiary of Biovertis AG, Vienna, since 2008. He is also the CEO of Biovertis which he joined in 2006.

His previous position was Managing Director at Kapsner & Schmid GmbH, a European corporate finance advisory firm focusing on healthcare and life sciences. During that time, he also held several management and executive positions at client companies in challenging start-up and turn-around situations. Before that he was an investment manager with GE Capital, a consultant with McKinsey & Company, and co-founder and Managing Director of the Bavarian Public Health Research Center in Munich, Germany.

Dr. Kapsner holds a medical degree from the University of Munich. He was a research fellow at the university's Department of Internal Medicine and its Department of Medical Informatics, Biometry and Epidemiology.

Company Profile

Morphochem AG (Munich) is a clinical-stage pharmaceutical company dedicated to the development of a novel quinolonyl-oxazolidinone antibacterial, MCB3681, the only intravenous therapy for Clostridium difficile infections currently in clinical development. Proof-of-Principle, safety and tolerability have been demonstrated in three phase 1 studies. The U.S. FDA accepted the IND for a phase 2 study, and granted QIDP and Fast Track designations in 2016.

Mode of action studies revealed that MCB3681 interacts with four different targets, resulting in superior activity, exceptionally low propensity for resistance development, and lack of cross-resistance to any established class of antibacterials. The compound's in vitro activity against more than 300 C. difficile clinical strains proved to be stronger than that of vancomycin and metronidazole, and comparable to fidaxomicin (MIC range: 0.008–0.5 mg/L). In a multiple-dose study performed at Karolinska results revealed high MCB3681 concentrations in feces after IV administration and an antibacterial effect on Gram-positive anaerobic and aerobic bacterial species in feces while sparing Gram-negatives, including Bacteroides spp. which are known to provide resistance against colonization.

For the further development and commercialization of MCB3681, the company is currently exploring financing and partnership options.

Morphochem is a 100% subsidiary of Biovertis AG (Vienna, Austria). Biovertis' majority shareholder is TVM Capital.

Morphochem Aktiengesellschaft für kombinatorische Chemie
Gmunder Str. 37a
81379 Munich
Germany

Contact:
Dr. Thomas Kapsner, CEO
t: +49 172 8535 720
m: thomas.kapsner@biovertis.de
www.morphochem.de

SESSION

How to create a business case with antimicrobials

Moderator: Peter West

Accelerating the antibiotics pipeline: CARB-X and AMRC

Dr. Peter Jackson

Executive Director

AMR Centre, Macclesfield

Dr Peter Jackson is Executive Director of AMR Centre – a UK public-private partnership focused on antimicrobial resistance R&D, and a member of the transatlantic CARB-X initiative.

An experienced life sciences entrepreneur, Dr Jackson is the founder of five life sciences ventures:

RedX Pharma plc – an emerging pharmaceutical company focused on developing new immunotherapy, oncology and anti-infective drugs;

ADC Biotechnology Ltd – focused on production of new antibody-based cancer therapeutics;

Yprotech Ltd – focused on development of new chemistry processes for pharmaceuticals and agrochemicals;

RedAg Crop Protection – developing the next generation of fungicides, herbicides and insecticides to overcome emerging resistant organisms in agriculture; and

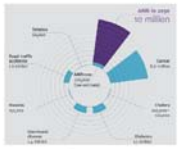
Bivictrix Therapeutics – a new start up developing innovative precision medicine approaches to Leukemia.

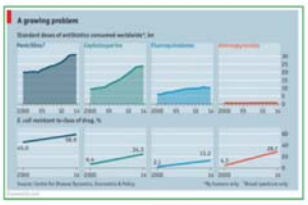
Dr Jackson has over 25 years in the sector, previously holding senior executive roles as a Commercial Director and then head of Avecia's Pharmaceutical Products business unit, following senior commercial and R&D positions at Zeneca and ICI.

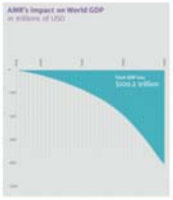
AMR Centre
BioHub
Mere side, Alderley Park
SK10 4TG Macclesfild
United Kindom

Tel.: +44 7711 796 690
Mail: peter.jackson@amrcentre.com

Growing Problems, Declining Solutions







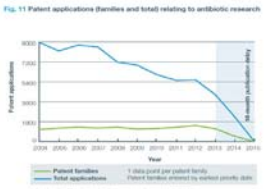
5,000 deaths per year in UK

25,000 deaths per year in EU

10 million deaths per year worldwide from resistant infection by 2050

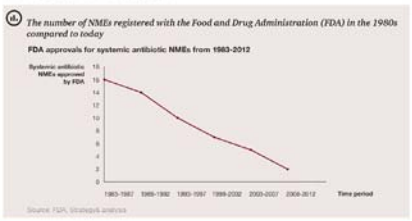
3.5% adverse impact on global GDP in next 35 years

$100 trillion lost from the world economy by 2050



Global patent applications for new antibiotics have halved from 2004 to 2013

Only 2 antibiotic NMEs registered with the FDA between 2008-2012, down from 16 in the past 30 years



CARB-X

AMR CENTRE

The Scale of the Challenge

Drug development stage	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	Year 11	Year 12	Year 13	Year 14
Hits	64													
LO			16											
PCDC					8									
IND ready						6								
Ph 1	Discovery		Translation				5				Clinical			
Ph 2									4					
Ph 3											2			
NDA													1	
Approved														1
Cost per drug per stage US$m	4		4		5	1	10		25		80	1		130
Total cost per stage US$m	256		20		40	6	50		100		160	1		633

Empirical success rates for antibiotics obtained from pharma industry publications

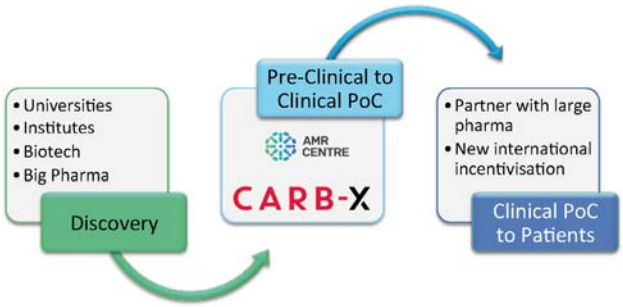
For one successful new antibiotic, we need at least 64 new projects coming out of discovery and 5 entering clinical trials

From start to end it will take 14 years and cost at least US$600m, and we need more than one new therapy

CARB-X

AMR CENTRE

Filling The Translation Gap



Funding Facilities People

CARB-X AMR CENTRE

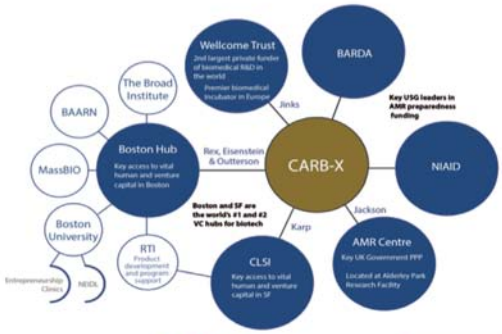
CARB-X Transatlantic Consortium

US Government funding, $250m over 5 years with additional contributions from Wellcome Trust and AMR Centre

First two calls for expressions of interest closed in September and October

Over 300 expressions of interest so far requesting over US$1bn in funding

Year 1 focus on supporting SMEs with innovative approaches to targeting urgent and serious Gram- infections



CARB-X AMR CENTRE

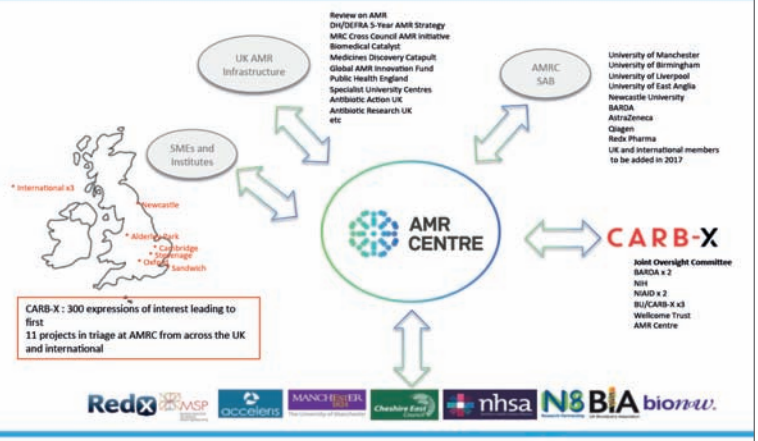
AMR Centre

Translational R&D centre to provide funding, capacity and capability

Regional public-private partnership with existing world class infrastructure and UK NHS clinical trial networks

Fast-track development from pre-clinical to clinical proof of concept

Partnering with SMEs, research institutes and academia to co-develop new treatments targeting AMR



CARB-X

AMR CENTRE

AMR CENTRE | The UK R&D Centre for Antimicrobial Resistance

Thank You

amrcentre.com

carb-x.org

CARB-X

AMR CENTRE

Combatting antimicrobial resistance: The SME perspective

Marie Petit

Coordinator

BEAM Alliance, Paris

Marie Petit is Coordinator of the BEAM Alliance, the European consortium of biotech companies combating antimicrobial resistance. In the meantime she is Partner at Villiger Valuation a Swiss-based consultancy for Life Sciences valuation with reknown expertise ranging from early stage project valuation, modeling of funds to support in licensing, trade sales and IPO situations. She holds a Master in Finance and Strategy from Sciences Po Paris and has been graduated with merit from the Scube, the dual track made by Sciences Po and University Pierre et Marie Curie (Paris VI) in Political & Fundamental Sciences. She brings to the BEAM Alliance her expertise in valuying pharmaceutical innovation from all different stakeholders' perspective to build strategies to sustainably reinvigorate R&D in the area of antibacterials. In 2008 she coordinated the French EU Presidency in Singapore.

VILLIGER VALUATION Sàrl
Bäumleingasse 2
4051 Basel
Switzerland

Tel.: +33 6 50 01 15 33
Mail: marie.petit@villigervaluation.ch

BEAM Alliance
c/o Da Volterra
Le Dorian B1
172 rue de Charonne
75011 Paris
France

Tel.: +33 6 50 01 15 33
Mail: marie.petit@beam-alliance.eu

Combatting antimicrobial resistance: The BioVersys case

Dr. Marc Gitzinger

CEO & Co-Founder

BioVersys AG, Basel

Marc Gitzinger is founder of BioVersys AG, a multi-award winning biopharmaceutical company focused on combatting antimicrobial resistance. Prior to BioVersys, he completed his studies in Biology at the University of Freiburg (Germany) and the University of Queensland (Australia). He holds a PhD in Biotechnology from the ETH Zurich. Marc gained additional business experience as Associate Intern at McKinsey & Company and insights to intellectual property rights at the patent offices Ernest T. Freylinger SA (Luxemburg) and Joachim Stuercken GmbH (Germany). Marc is winner of two Venture Leaders awards (2008 and 2016) and he is vice president of the Board of the BEAM Alliance.

BioVersys AG
c/o Technologiepark Basel
Hochbergerstrasse 60c
4057 Basel
Switzerland

Tel.: +41 61 633 22 50
Mail: marc.gitzinger@bioversys.com

BEAM Alliance

http://beam-alliance.eu/

Board Members:
Florence Séjourné, Da Volterra, France
Marc Gitzinger, BioVersys AG, Switzerland
Holger Schmoll, Aicuris, Germany
Mark Jones, Basilea, Switzerland
Marc Lemonnier, Antabio, France

Executive coordinator:
Marie Petit, BEAM-Alliance; marie.petit@beam-alliance.eu

The SME Perspective

Berlin, February 24

SME's project fuel the R&D pipeline

from early to late clinical stage

BEAM ALLIANCE IN NUMBERS

50 members

+250 products in preclinical research

+32 products in clinical development

1 product in the market

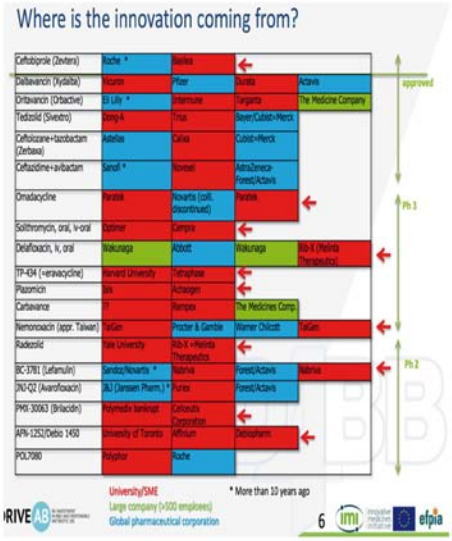
2/3 of small antibacterial therapies

1/3 of alternative strategies (vaccines, peptides, antibodies, phages, micorbiome modulators,...)

1 M€ - 3 M€ between spent in R&D / year

800 employees

80% in R&D



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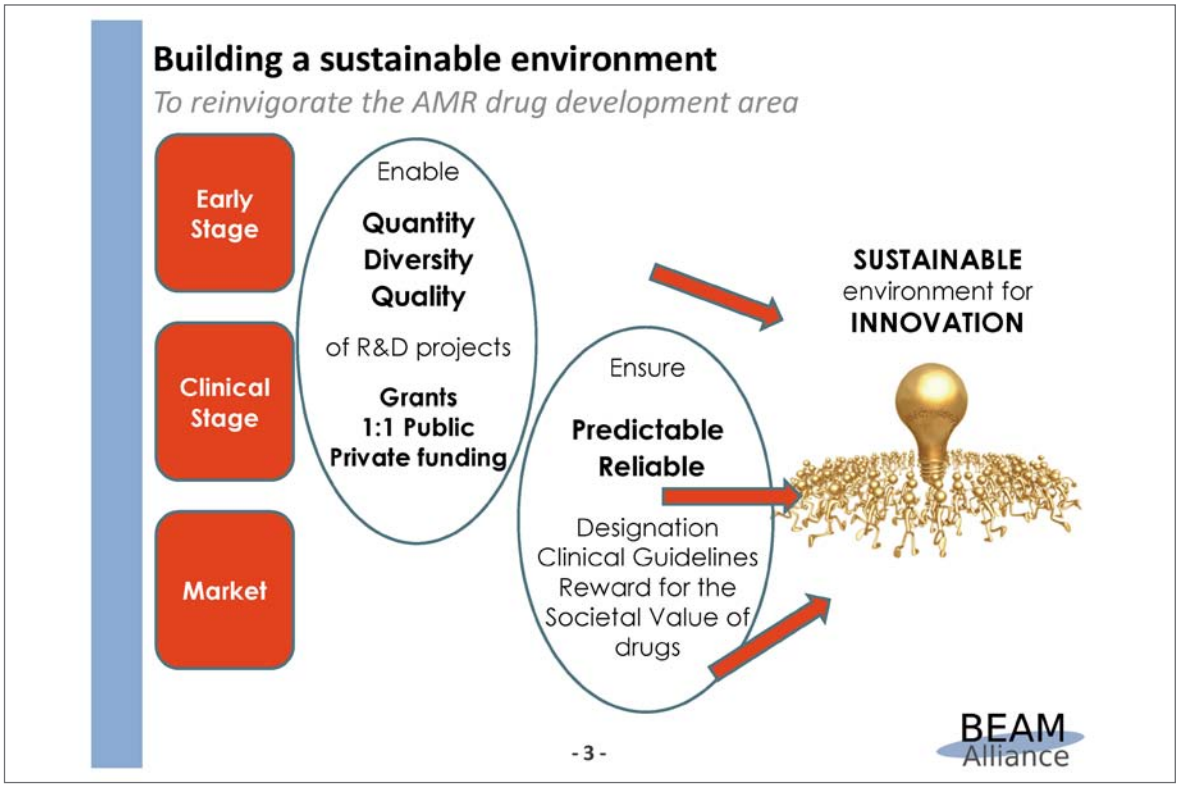
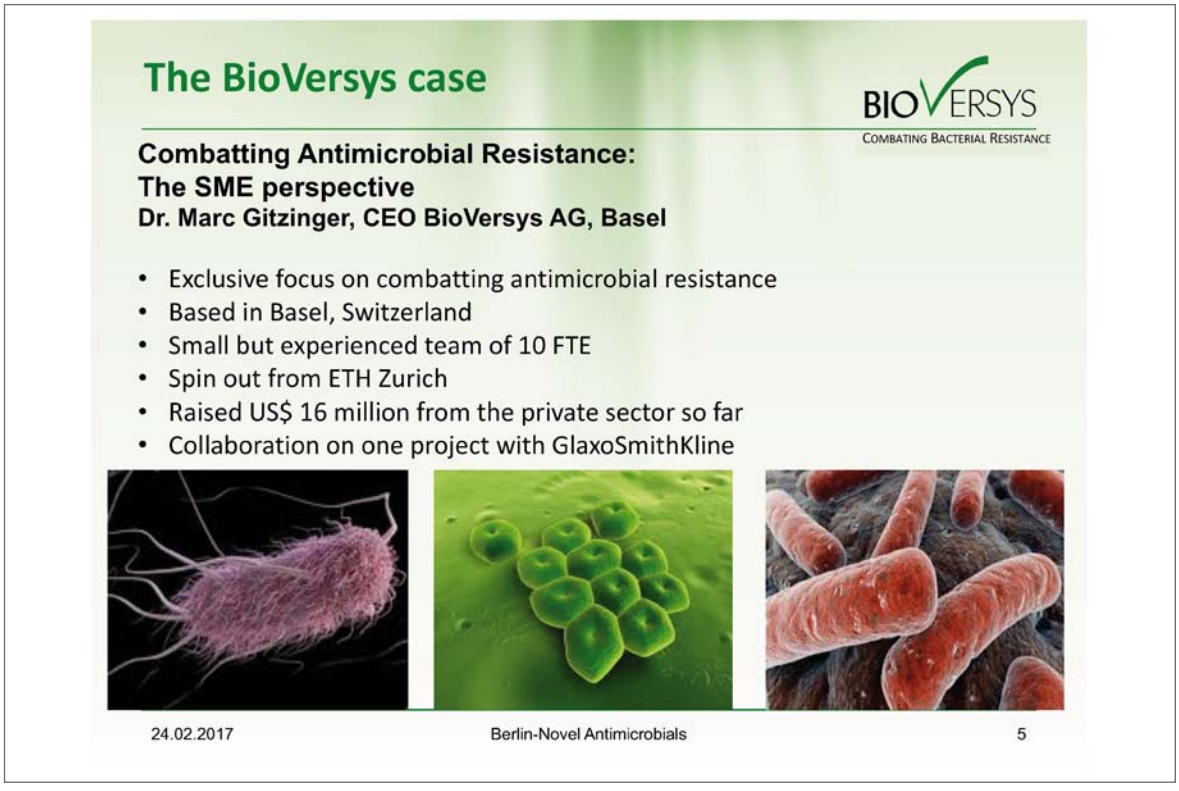
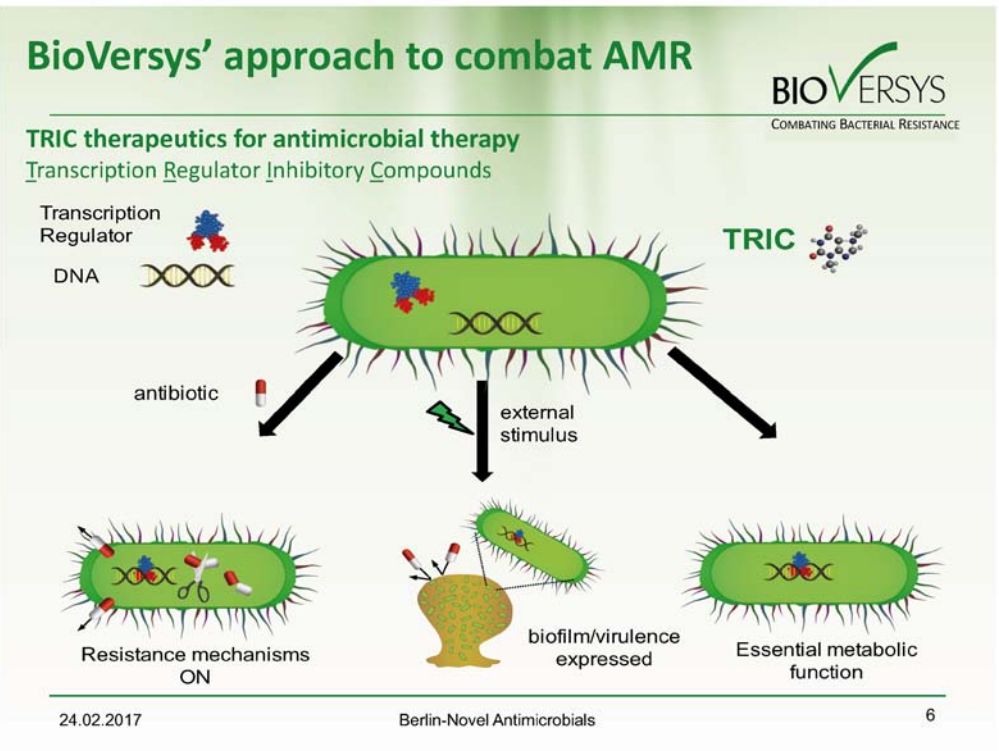
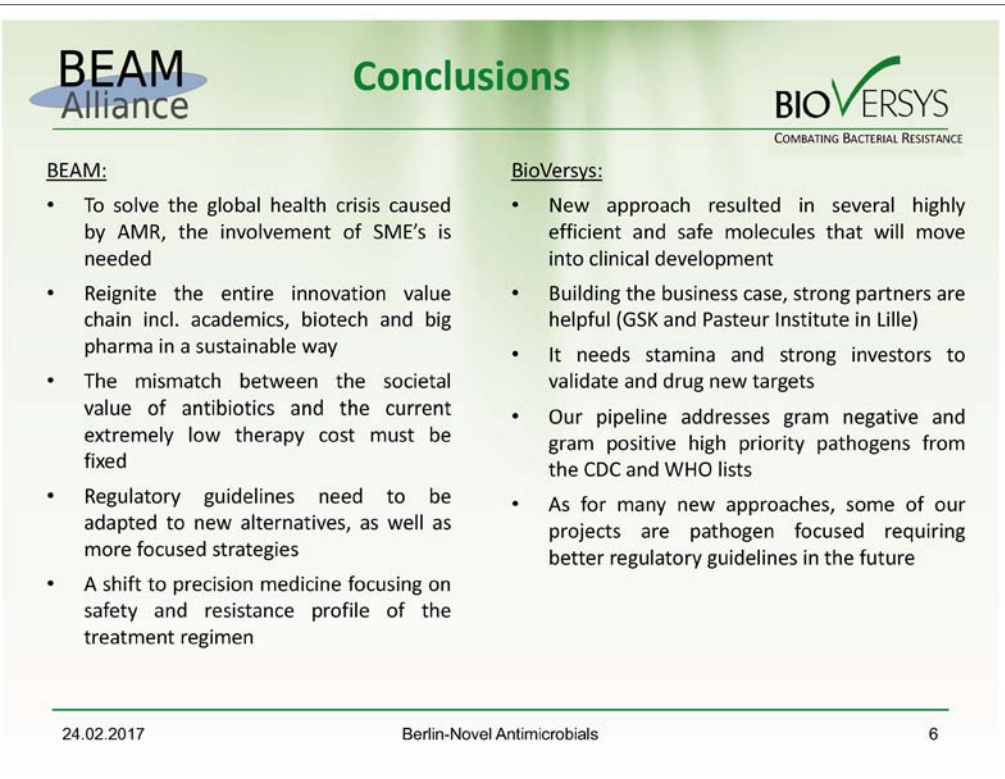
BEAM Alliance


Building a sustainable environment
To reinvigorate the AMR drug development area
Early Stage
Clinical Stage
Market
Enable
Quantity
Diversity
Quality
of R&D projects
Grants
1:1 Public
Private funding
Ensure
Predictable
Reliable
Designation
Clinical Guidelines
Reward for the
Societal Value of
drugs
SUSTAINABLE
environment for
INNOVATION
- 3 -
BEAM
Alliance


The BioVersys case
BIOVERSYS
COMBATING BACTERIAL RESISTANCE
Combatting Antimicrobial Resistance:
The SME perspective
Dr. Marc Gitzinger, CEO BioVersys AG, Basel
• Exclusive focus on combatting antimicrobial resistance
• Based in Basel, Switzerland
• Small but experienced team of 10 FTE
• Spin out from ETH Zurich
• Raised US$ 16 million from the private sector so far
• Collaboration on one project with GlaxoSmithKline
24.02.2017
Berlin-Novel Antimicrobials
5


BioVersys' approach to combat AMR
BIOVERSYS
COMBATING BACTERIAL RESISTANCE
TRIC therapeutics for antimicrobial therapy
Transcription Regulator Inhibitory Compounds
Transcription Regulator
DNA
TRIC
antibiotic
external stimulus
Resistance mechanisms ON
biofilm/virulence expressed
Essential metabolic function
24.02.2017
Berlin-Novel Antimicrobials
6


BEAM Alliance
Conclusions
BIOVERSYS
COMBATING BACTERIAL RESISTANCE
BEAM:
• To solve the global health crisis caused by AMR, the involvement of SME's is needed
• Reignite the entire innovation value chain incl. academics, biotech and big pharma in a sustainable way
• The mismatch between the societal value of antibiotics and the current extremely low therapy cost must be fixed
• Regulatory guidelines need to be adapted to new alternatives, as well as more focused strategies
• A shift to precision medicine focusing on safety and resistance profile of the treatment regimen
BioVersys:
• New approach resulted in several highly efficient and safe molecules that will move into clinical development
• Building the business case, strong partners are helpful (GSK and Pasteur Institute in Lille)
• It needs stamina and strong investors to validate and drug new targets
• Our pipeline addresses gram negative and gram positive high priority pathogens from the CDC and WHO lists
• As for many new approaches, some of our projects are pathogen focused requiring better regulatory guidelines in the future
24.02.2017
Berlin-Novel Antimicrobials
6

Notes

AntibioTx ApS

AntibioTx ApS
Kemitorvet 220
2800 Kgs. Lyngby
Denmark

Contact:
Rasmus Toft-Kehler, CEO
t: +45 40 10 30 44
m: rasmus.toft-kehler@
antibiotx.com
www.antibiotx.com

Rasmus Toft-Kehler

CEO & Co-Founder

Rasmus Toft-Kehler is a dedicated entrepreneur and have been involved with a number of new ventures including Clinical-Microbiomics A/S. Prior to his entrepreneurial career, Rasmus worked in M&A (Goldman Sachs and Gudme Raaschou), management consulting (Booz Allen Hamilton) and in a family-owned enterprise. Rasmus holds an executive degree in entrepreneurial leadership from Harvard Business School and a degree in finance and business administration from New York University and Copenhagen Business School.

Company Profile

AntibioTx is a privately held, clinical stage, pharmaceutical company dedicated to the development of a novel class of antibiotics with a new mechanism of action. Antibiotic candidates are being developed to treat infections that are currently causing harm to millions of patients worldwide. ATx201 and ATx301 are the lead candidates and first-in-class antibiotics for topical treatment of multidrug resistant skin infections and microbiome related dermatological disorders.

The compound class offers a number of unique advantages including:

1. Novel mechanism of action
2. >10.000-fold better than marketed antibiotics in delaying the onset of de novo resistance
3. Effectively overcomes current multi-drug resistance
4. Clinical stage lead candidates – ATx201 and ATx301 – with proven human safety
5. Chemical scaffold provide opportunities to develop new compositions of matter

The AntibioTx team and advisors account for more than 20 drug approvals generating annual revenues >5 B USD.

NovaBiotics Ltd

Dr. Deborah A. O'Neil

CEO & CSO

A biotechnologist with two decades of experience in the field of anti-infectives research & drug development, Deborah studied immunology at University College London and then worked in internationally acclaimed laboratories in San Diego and Ghent before moving to Aberdeen. It was here where, in order to fully develop the commercial potential of her platform of novel antibacterial and antifungal therapies, she founded NovaBiotics in 2004. Deborah has since grown the business – as its Chief Executive & Scientific Officer – into a leading global biotechnology company with a portfolio of clinical-stage and preclinical anti-infective drug candidates for medically unmet infectious diseases. Deborah is editor of the European Biopharmaceutical Review and International Pharmaceutical Technology, a member of the Scottish Life Science Industry Leadership Group and sits on the Advisory Board of the Scottish Life Sciences Association. Deborah is also a member of the newly formed Life Sciences board of Opportunity North East and is also a proud Trustee of Crohn's in Childhood Research Association.

Company Profile

- A leading global anti-infectives biotechnology company
- Based in Aberdeen, UK; a key international cluster for biologics drug discovery & anti-infectives R&D
- Three clinical-stage products, robust earlier-stage pipeline & unique patented platform technology
- Strong lead product candidates in Novexatin®, a topical treatment for nail fungus ($6 bn global market; 2017) &
- Lynovex® for CF exacerbations & long term therapy (>$5 Bn market; 2017)
- Led by an impressive management team with proven track record, supported by in-house scientific expertise
- Developing proprietary medicinal candidates that are a potential solution to a 'global crisis' of antimicrobial drug resistance
- Targeting economically & clinically significant markets with breakthrough antimicrobial technology

NovaBiotics Ltd
Cruickshank Building
Craibstone, Aberdeen
AB21 9TR
United Kingdom

Contact:
Dr. Deborah A. O'Neil, CEO
t: +44 1224 711377
m: deborah@novabiotics.co.uk
www.novabiotics.co.uk

Adrenomed AG

Dr. Frauke Hein

CBO

Dr. Frauke Hein, Co-Founder and Chief Business Officer (CBO) of Adrenomed AG, is Biologist with decades of experience in the diagnostic and biotechnology industry. Before establishing Adrenomed she was at BRAHMS AG / Thermo Fisher Scientific responsible for strategic global R&D projects, in the field of cardiology, liver disease, sepsis and neurodegeneration. Dr. Hein is Executive Board Member of the InfectControl 2020 Consortium, Member of the Board of Trustees of Technology Foundation Brandenburg and was Jury Member of the Berlin-Brandenburg Business Innovation Award.

Adrenomed AG
Neuendorfstr. 15a
16761 Hennigsdorf
Germany

Contact:
Dr. Frauke Hein, CBO
t: +49 3302 20778 14
m: fhein@adrenomed.com
www.adrenomed.com

Company Profile

Adrenomed has a clear mission: to improve survival by improving vascular integrity in critically ill patients. Clinical lead product is the first-in-class drug candidate Adrecizumab, a humanized monoclonal antibody targeting Adrenomedullin, an essential hormone that controls endothelial barrier function and prevents vascular leakage. We demonstrated that Adrecizumab effectively counteracts loss of vascular integrity and edema formation, a hallmark of a variety of severe acute indications with high unmet need and the final common path of all infections. The groundbreaking Mode of Action combines high efficacy in a variety of preclinical models mimicking standard of care treatment on ICU with excellent safety and tolerability. Adrecizumab will be tested in a first Phase II study in patients with early septic shock. Adrenomed AG is a privately-financed biopharmaceutical company based in Hennigsdorf near Berlin

Notes

SESSION

Think beyond – technology highlights from academic research

Chair: Andrew Ullmann

Moderation

Prof. Dr. Andrew J. Ullmann

Head of Infectious Diseases

Universitätsklinik Würzburg, Julius-Maximilians-Universität

Andrew Ullmann is a full-professor for infectious diseases and internal medicine, and head of the Division of Infectious Diseases in the Department of Internal Medicine II of the Julius-Maximilians-University of Würzburg, Germany. Prof. Ullmann is board certified in internal medicine, emergency medicine, haematology and oncology, and infectious diseases. He was trained in Bochum, Mainz, Germany, and further trained in infectious diseases in New York City and at Harvard Medical School, Boston Massachusetts.

He is the author or coauthor of numerous peer-reviewed articles, which have been published in many journals, including The New England Journal of Medicine and The Lancet. He is co-editor for Infection, Mycoses and Journal of Antimicrobial Chemotherapy. His scientific interests evolve around clinical research of infections particularly in patients who are severely immunocompromised.

Prof. Ullmann is chair of the Infectious Diseases section within the German Association of Internal Medicine Professionals (BDI), and until 2016 was the chairperson of EFISG within the ESCMID (European Society of Clinical Microbiology and Infectious Diseases). He is also a member of several other professional societies.

Universitätsklinik Würzburg
Julius-Maximilians-Universität
Medizinische Klinik und Poliklinik II
Oberdürrbacher Str. 6
97080 Würzburg
Germany

Tel.: +49 931 201 40115
Mail: ullmann_a@ukw.de

Prof. Dr. Ir. Yves Briers

Head of the Laboratory of Applied Biotechnology

Ghent University

Yves Briers is co-inventor of the concept of Artilysin®s, novel enzyme-based antibiotics, which are commercialized as a technology platform by Lysando AG. He held postdoc positions at ETH Zurich (Switzerland) with a long-term fellowship of the European Molecular Biology Organization (EMBO) and at KU Leuven (Belgium).

In May 2015 he was appointed as assistant professor to head the Laboratory of Applied Enzymology at Ghent University. His research interests are the synthetic biology of modular proteins with applications in industrial and medical biotechnology.

Yves Briers is inventor on seven patents and has published over 40 international, peer-reviewed publications in the field of the development and analysis of antimicrobials.

Ghent University
Laboratory of Applied Biotechnology
Campus Schoonmeersen
Valentin Vaerwyckweg 1
9000 Ghent
Belgium

Tel.: +32 9 243 24 53
Mail: yves.briers@ugent.be

Artilysin®s: A novel class of enzyme-based antibacterials inspired by bacteriophages

Artilysin®s represent a novel, promising class of enzyme-based antibacterials, combining the lytic power of bacteriophage-encoded endolysins and outer membrane penetrating peptides. Selected peptides that locally destabilize the outer membrane of Gram-negative bacteria have been covalently fused to endolysins that degrade the peptidoglcyan layer.

These peptides promote the transfer of the fused endolysin to the peptidoglycan layer across the outer membrane. The enzymatic nature of Artilysin®s comes along with disruptively new features for antibacterials. They are rapid and act upon contact (time-lapse microscopy has shown that cells are killed within seconds), they show no cross-resistance with existing antibiotics due to the novel mode-of-action and do not provoke resistance development, and they kill metabolically dormant persisters that contribute to recurrent chronic infections.

Recently, we have shown that the Artilysin® approach also results in strongly improved endolysin-based antibacterials against Gram-positive bacteria.

Prof. Dr. Stephan A. Sieber

Chair of Organic Chemistry II

Technical University Munich, Garching

Since 2009:	Full professor for organic chemistry (OCII) at Technical University Munich (TUM), Germany
2006 – 2009:	Independent research position at the Ludwig-Maximilian University of Munich (LMU) funded by the Emmy Noether program. Mentor: Prof. Thomas Carell
2004 – 2006:	Postdoctoral research with Prof. Benjamin F. Cravatt at the Scripps Research Institute in La Lolla, USA
10/2002 – 03/2004:	Research for doctoral thesis with Prof. Mohamed A. Marahiel at Philipps-University in Marburg, Germany. “Nonribosomal Peptide Synthetases: Quaternary Structure and Chemoenzymatic Synthesis of Macrocyclic Peptides”. Grade: “With distinction”
12/2001 – 12/2002:	Research for doctoral thesis in the laboratory of Prof. Christopher T. Walsh at Harvard Medical School in Boston, USA
09/1999 – 03/2000:	Exchange student at the University of Birmingham, UK
10/1996 – 08/2001:	Graduate student of chemistry, Philipps-University Marburg, Germany. Diploma thesis under the guidance of Prof. Mohamed A. Marahiel “Investigation of the quatenary structure of nonribosomal peptide synthetases”. Grade: 1.0

Technical University Munich (TUM)
Department of Chemistry
Lichtenbergstr. 4
85747 Garching

Tel.: +49 89 289 13301
Mail: stephan.sieber@mytum.de

Chemical tools to manipulate bacterial virulence

S. A. Sieber, Munich/D, P. Kleiner, Munich/D, E. Kunold, Munich/D, C. Fetzer, Munich/D, M. Stahl, Munich/D,
Prof. Dr. Stephan A. Sieber, TUM, Lichtenbergstr. 4, 85747 Garching

Multiresistant bacterial pathogens such as Methicillin-resistant *Staphylococcus aureus* (MRSA) are responsible for a variety of severe infections that pose a significant threat to global health. To approach this challenge new chemical entities with an unprecedented mode of action are desperately needed. This presentation will cover our latest efforts to identify new anti-bacterial targets and corresponding chemical inhibitors with the main emphasis on caseinolytic protease P (ClpP).

The barrel-shaped ClpP protease is a highly conserved virulence regulator in bacterial pathogens. Genetic ClpP knockouts in *S. aureus* revealed a reduction in virulence, i.e. the expression of bacterial toxins, resulting in attenuated infections in murine abscess models.[1] Similarly, the same phenotype was observed upon the chemical inhibition of ClpP with beta-lactones, the only specific inhibitors reported for ClpP to date.[2] These tool compounds helped to dissect the mechanism of inhibition which is based on binding into a hydrophobic pocket that in turn destabilizes the tetradecamer and induces dissociation into inactive heptamers.[3] Complementary structural studies of inhibitor binding reveal a highly dynamic complex that is regulated by conformational switching[4] via a network of catalytic residues that link enzyme activity with oligomerization.[5] Thus inhibition via de-oligomerization represents an attractive strategy to eliminate bacterial virulence and attenuate pathogenesis *in vivo*. A second generation of covalent ClpP inhibitors with superior potency, inhibition kinetics, stability and specificity will be presented as well.

The anti-virulence mode of action and the corresponding absence of resistance development in *in vitro* assays could furthermore contribute to longer lasting drugs.

Literature:
[1] D. Frees, S. N. Qazi, P. J. Hill, H. Ingmer, *Mol Microbiol* **2003**, 48, 1565-1578. [2] T. Böttcher, S. A. Sieber, *J Am Chem Soc* **2008**, 130, 14400. [3] a) M. Gersch, F. Gut, V. S. Korotkov, J. Lehmann, T. Bottcher, M. Rusch, C. Hedberg, H. Waldmann, G. Klebe, S. A. Sieber, *Angew Chem Int Ed Engl* **2013**, 52, 3009; b) M. Gersch, R. Kolb, F. Alte, M. Groll, S. A. Sieber, *J Am Chem Soc* **2014**, 136, 1360. [4] M. Gersch, K. Famulla, M. Dahmen, C. Gobl, I. Malik, K. Richter, V. S. Korotkov, P. Sass, H. Rubsamen-Schaeff, T. Madl, H. Brotz-Oesterhelt, S. A. Sieber, *Nat Commun* **2015**, 6, 6320. [5] E. Zeiler, A. List, F. Alte, M. Gersch, R. Wachtel, M. Poreba, M. Drag, M. Groll, S. A. Sieber, *Proc Natl Acad Sci U S A* **2013**, 110, 11302.

Michael McDonough, PhD

Senior Research Scientist

University of Oxford

Michael McDonough received his PhD in Biophysics, with a focus in X-ray crystallography, from the University of Connecticut in 2000 where he made significant contributions to understanding how β-lactam antibiotic targets bind to their substrates.

He then spent two years at the University of Copenhagen honing his structural skills before settling in Oxford in 2003 where he has since been instrumental in studies of 2OG oxygenases involved in β-lactam biosynthesis, PBPs, SBLs and MBLs.

He has authored over 80 papers and has helped to co-author several patents in these areas

University of Oxford
Chemistry Research Laboratory
Mansfield Road
OX1 3TA Oxford
United Kingdom

Tel.: +44 1865 275 629
Mail: michael.mcdonough@chem.ox.ac.uk

Defeating carbapenemases – escalating the microbial chemical-warfare arms-race

Due to their efficacy and safety β-Lactams such as penicillins and cephalosporins are still the most prescribed antibiotics in the clinic worldwide. The metallo-β-lactamases (MBLs) catalyse hydrolysis of β-Lactam antibiotics and have emerged as a major clinical threat. Carbapenems, β-lactam antibiotics once known as "the last line of defense", are not easily destroyed by some serine β-lactamases but are highly susceptible to most MBLs. The eminent spread of the New Delhi MBLs (NDMs) is currently of greatest clinical concern. A strategy that has been highly successful in treating SBL resistant infections is the co-administration of SBL inhibitors (ie. Augmentin). To date there are no clinically available MBL inhibitors. Global antibiotic research has failed to keep up with the growing need for new antibiotics to combat resistance, primarily for socio-economic reasons. Our group has developed a technological platform for identifying and characterising MBL inhibitors. In collaboration with the Innovative Medicines Initiative (IMI) European Lead Factory (ELF), a public-private partnership, we have identified several classes of potent broad spectrum MBL inhibitors, that when combined with the carbapenem meropenem show efficacy against a wide panel of clinically resistant strains. We have recently progressed our lead compound series into a collaboration with the IMI New Drugs for Bad Bugs (ND4BB) ENABLE consortium drug-discovery platform and aim to reach the IND stage. Outside of the IMI collaboration we are advancing other leads including pan-SBL/MBL inhibitors.

Prof. Dr. Mark Brönstrup

Head of the Cemical Biology Department

Helmholtz Centre for Infection Research, Braunschweig

Mark Brönstrup studied chemistry and obtained his PhD from the TU Berlin in 1999. He joined Aventis in 2000 as a lab head for mass spectrometry and spent a research sabbatical at Harvard Medical School in 2003. Between 2005 and 2010, he was leading the Natural Products Science section at Sanofi Aventis in Frankfurt.

Between 2010 and 2013, he was managing sections dealing with biomarkers, bioimaging & biological assays. Since December 2013, he has been head of the Chemical Biology Department at the Helmholtz Centre for Infection Research in Braunschweig and W3 Professor at the University of Hannover. His research is focused on the discovery, the characterization and the optimization of novel antiinfective drugs.

Helmholtz Centre for Infection Research
Department of Chemical Biology
Inhoffenstrasse 7
38124 Braunschweig
Germany

Tel.: +49 531 6181 3400
Mail: mark.broenstrup@helmholtz-hzi.de

Chemical biology directed to anti-infective drug discovery

Infections caused by pathogenic bacteria represent a major health threat that is expected to rise further in the future. The need for novel antibiotics is currently not met by R&D efforts, in particular in the area of infections caused by Gram-negative bacteria. A main scientific hurdle is the lack of understanding how to assure a sufficient translocation of bioactive molecules across the Gram-negative cell wall.

The Helmholtz Centre for Infection Research embarks on the discovery of novel natural products with gram negative activity. The optimization of two series, the cystobactamids and the chelocardins, will be presented.

In an alternative approach, we induce an active transport of small molecules into Gram negative bacteria and develop methods to quantify such uptake. We report a series of theranostics agents based on 1,4,7,10-tetraazacyclododecane-1,4,7,10-tetraacetic acid amide (DOTAM) derivatives comprising siderophores that actively target bacteria, inhibit bacterial growth and demonstrate efficacy to visualize bacterial infections in mice by optical imaging *in vivo*.

Prof. Dr. Andreas Peschel

Professor of Microbiology

University of Tübingen

Andreas Peschel studied Biology in Bochum and Tübingen, Germany, and obtained Diploma and PhD degrees in Microbiology. He held postdoctoral positions in the labs of Friedrich Götz in Tübingen and of Jos van Strijp in Utrecht (The Netherlands) focusing on Staphylococcus aureus cell wall and host/pathogen interaction.

After a period as Assistant Professor at the Faculty of Biology he accepted a call to the Medical Microbiology and Hygiene Department as a Professor of Cellular and Molecular Microbiology in Tübingen. His lab studies staphylococcal biology with special interests in teichoic acids, evasion of antimicrobial defense mechanisms, and proinflammatory bacterial molecules.

University of Tübingen
Infection Biology Department
Auf der Morgenstelle 28, E8P16
72076 Tübingen
Germany

Tel.: +49 7071 29 75935
Mail: andreas.peschel@uni-tuebingen.de

Antibiotic-resistant pathogens in human microbiota: fighting the enemy within

Antibiotic-resistant bacterial pathogens (ARBPs) used to spread mostly among risk patients in healthcare settings. This paradigm is about to change because new types of ARBPs do not adhere to this rule: they spread in the community, colonizing the microbiota of healthy and diseased humans, and enter hospitals with patients on admission. Being ARBP-colonized significantly increases the risk of a patient to acquire bloodstream or other invasive ARBP infections. Therefore, selective decolonization agents are urgently needed to limit the alarming rise of antibiotic-resistant infections caused by endogenous bacterial pathogens.

We recently reported that bacterial strains isolated from the human nose microbioms frequently produce antimicrobial molecules with highly variable activity spectra. Analysis of a compound with activity against the major human pathogen and nasal colonizer Staphylococcus aureus revealed the first example of a novel microbiota-derived antibiotic, lugdunin, whose production by commensal bacteria impairs nasal colonization by S. aureus. Human microbiota may thus be a rich source for new antimicrobials, which may not only lead to new therapeutic agents but also to innovative ways of ARBP decolonization to prevent infections.

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Prof. Aras Kadioglu

Bacterial Pathogenesis, Institute of Infection & Global Health

University of Liverpool

Aras Kadioglu was born in Cambridge, but grew up in Liverpool, Washington DC and Istanbul before returning to the UK to read for my BSc in Microbiology at the University of Leicester, where he was also awarded as PhD in Immunology in 1996 on the role of CD4 T cell recirculation and adhesion in chronic inflammatory disease. He continued the theme of host adhesion molecule expression during inflammation in his first postdoctoral position at the Hammersmith Hospital, Imperial College London before moving back to the University of Leicester to start working on host immune responses to pneumococcal colonisation and invasive disease.

He was promoted to Lecturer in Respiratory Infection in 2005, then Reader in 2009. He finally returned to Liverpool as Professor of Bacterial Pathogenesis in 2011 at the Institute of Infection & Global Health.

Aras primary area of expertise is pathogenesis of Streptococcus pneumoniae and the interplay between bacterial virulence and cellular innate and adaptive immunity. These research interests have more recently been expanded to include Streptococcus pyogenes, Pseudomonas aeruginosa and Staphylococcus aureus. In his group they have developed clinically relevant mouse models of respiratory and systemic infection to elucidate mechanistic understanding of the disease processes involved and the host immune responses to infection. As part of these efforts, he also has research projects on the development of novel anti-bacterial therapeutics and new generation vaccines through the Liverpool Centre for Global Vaccine Research. Aras most recent publications in these areas have been in Nature Biotechnology, Nature Communications, American Journal of Respiratory and Critical Care Medicine, Journal of Allergy and Clinical Immunology and PLoS Pathogens amongst others. His research is funded by MRC Programme and DPFS MICA grants, JPI-AMR funding and by Meningitis Now as well as by industrial partners including GSK and Roche.

University of Liverpool
Department of Clinical Infection Microbiology & Immunology
Institute of Infection & Global Health
The Ronald Ross Building
8 West Derby St, Liverpool
United Kingdom

Tel.: +44 151 79 59612
Mail: a.kadioglu@liverpool.ac.uk

Notes

SESSION

Start-up competition & investors talk

Moderator: Peter West

Start-up competition & investors talk

The development of new therapeutics to combat antimicrobial resistance is more relevant today than ever before. Although the business environment is tough, start-ups in Europe advance new technologies in the field. The session will highlight four new ventures and will discuss the topic from an investor's perspective.

Rasmus Toft-Kehler, CEO and Co-Founder, AntibioTx ApS, Lyngby, Denmark
Mail: rasmus.toft-kehler@antibiotx.com Tel.: +45 40 10 30 44

Rasmus Toft-Kehler is a dedicated entrepreneur and have been involved with a number of new ventures including Clinical-Microbiomics A/S. Prior to his entrepreneurial career, Rasmus worked in M&A (Goldman Sachs and Gudme Raaschou), management consulting (Booz Allen Hamilton) and in a family-owned enterprise.

Rasmus holds an executive degree in entrepreneurial leadership from Harvard Business School and a degree in finance and business administration from New York University and Copenhagen Business School.

Dr. Holger Reithinger, Partner, Forbion Capital Partners, Munich, Germany
Mail: holger.reithinger@forbion.com Tel.: +49 89 41 6161 950

Holger Reithinger joined Forbion Capital Partners in 2010 and heads the German Office in munich. He started his career in Venture Capital in 1997 as an Investment Manager at Technologieholding VC GmbH which at that time was one of the leading German Venture Capital firm. Technologieholding was acquired by the 3i Group in early 2000, where Holger became a Director at its Germany's healthcare practice. Following this assignment, he became Principal and later Partner at Global Life Science Ventures, a well-established life sciences-focused partnership with offices in Switzerland and Germany.

Holger has served on the Boards of numerous life sciences companies including Epigenomics (IPO 2004), MBT (assets sold to Medigene AG), 4SC (IPO 2005), NeurogesX (IPO 2007), Fibrex Medical (assets licensed to Ikaria Inc.), Agendia BV and Santaris A/S (sold to Roche 2014). Holger holds board seats at Curetis NV (IPO 2015), Cellnovo Group S.A. (IPO 2015), Allecra Therapeutics GmbH and Rigontec GmbH.

Olivier Litzka, PhD, Partner, Edmond de Rothschild, Paris, France
Mail: o.litzka@edr.com Tel.: +33 140172746

Olivier Litzka is a partner at Edmond de Rothschild Investment Partners' (EdRIP) since he joined the firm in 2006. He invests in Biotechnology and Medtech companies in Europe and the US. He serves on the board of Allecra Therapeutics (St Louis), Autonomic Technologies Inc. (Redwood City), Noxxon Pharma (Berlin), JenaValve (Irvine/Munich), and SuperSonic Imagine (Aix en Provence). Up until its acquisition by AstraZeneca, he was also a member of the board of Novexel (France), as well as a member of the board of Endosense (Geneva) up until the company's acquisition by St Jude Medical and a member of the board of Sapiens Steering Brain Stimulation (Eindhoven) up until its acquisition by Medtronic. Until end of 2016, he was also member of the board of public company Probiodrug (Halle).

Before joining EdRIP, Olivier spent six years with 3i's life science venture capital practice, based first in Munich and then in Paris. In this position, he served on the boards of several portfolio companies and made a range of international investments. Before joining 3i in 2000, he worked as a strategy consultant with Mercer Management Consulting, both in Munich and Paris. Olivier holds a PhD in molecular microbiology from the Institut für Mikrobiologie at the University of Munich and performed his scientific research work over several years in Munich and Oxfor

Dr. Marc Gitzinger, CEO & Co-founder, BioVersys AG, Basel, Switzerland
Mail: marc.gitzinger@bioversys.com Tel.: +41 61 633 22 50

Marc Gitzinger is founder of BioVersys AG, a multi-award winning biopharmaceutical company focused on combatting antimicrobial resistance. Prior to BioVersys, he completed his studies in Biology at the University of Freiburg (Germany) and the University of Queensland (Australia). He holds a PhD in Biotechnology from the ETH Zurich. Marc gained additional business experience as Associate Intern at McKinsey & Company and insights to intellectual property rights at the patent offices Ernest T. Freylinger SA (Luxemburg) and Joachim Stuercken GmbH (Germany). Marc is winner of two Venture Leaders awards (2008 and 2016) and he is vice president of the Board of the BEAM Alliance.

Auspherix Ltd

Company Profile

Auspherix is an early-stage biotech developing a novel class of broad-spectrum antibiotics based upon its proprietary organogold chemistry platform. With potent activity against the ESKAPE pathogens, including life-threatening multi-drug resistant Gram-negative bacteria, its proprietary compounds have the potential to help address the global AMR healthcare crisis. The company's lead project, which is being developed for the treatment of complicated urinary tract infections, is currently in lead optimisation and is expected to progress into FTIH studies in early 2019.

The Presenter

Neil Miller trained as an organic chemist at the University of Liverpool and The Scripps Research Institute before entering the pharmaceutical industry as a medicinal chemist. During a career spanning almost two decades with GlaxoSmithKline (GSK), Neil held a variety of senior scientific and management roles, including that of Site Head at GSK's R&D centre in Singapore. Neil has extensive experience of progressing discovery projects through lead optimisation and into early clinical development. In 2015 Neil joined Auspherix as CSO and then moved into his current role as CEO in 2016.

auspherix

Founded:	**2013**	Employees:	**8**
Location:	**Stevenage, United Kingdom**		
Investors:	**Brandon Capital, Touchstone Innovations**		
Market:	**Pharmaceutical and/ or biotech companies with expertise in antibiotic medicine development**		

Auspherix Ltd
Stevenage Bioscience Catalyst, Gunnels Wood Road,
Stevenage, Herts, SG1 2FX, United Kindom
Tel.: +44 1438 906755
Web: www.auspherix.com

Contact: Neil Miller, CEO
Mail: neil.miller@auspherix.com

Immunethep SA

Company Profile

IMMUNETHEP discovered a novel mechanism of immunosuppression, which is shared by different pathogenic bacteria. By targeting this mechanism we are developing broad coverage Immunotherapy effective against multidrug resistant (MDR) bacteria. IMMUNETHEP has a global and breakthrough solution for an unmet medical need, Anti-microbial Resistance. With one single immunotherapy Immunethep is able to prevent the bacterial infections from the most life threatening bacteria, namely: E. coli, K. pneumonia, S. aureus, S. pneumonia and S. agalactiae.

The Presenter

Bruno Santos is Immunethep's CEO, a company that is developing a breakthrough solution to minimise the Multi-Drug Resistance Bacteria problem.

He is a Biological Engineer and an MBA. Bruno is a venture catalyst willing to apply time, effort and resources on understanding the underlying potential of scientific research, focused on creating ventures that transform and maximize scientific research's potential for society's use and benefit.

IMMUNETHEP

Founded:	**2014**	Employees:	**8**
Location:	**Cantanhede, Portugal**		
Investors:	**Portugal Ventures**		
Market:	**Anti-bacterial Vaccines, Anti-bacterial Antibodies**		

Immunethep SA
Biocant Park, Núcleo 04 Lote 3, 3060-197 Cantanhede, Portugal
Tel.: +351 231 419 042
Web: www.immunethep.com

Contact: Bruno Santos, CEO
Mail: info@immunethep.com

QureTech Bio AB

Company Profile

QureTech Bio defeats antibiotic resistance by boosting and restoring antibiotic efficiency. I. Healthcare Associated Infections caused by pathogens like Enterococcus faecalis (VRE), Streptococcus aureus (MRSA) or Clostridium difficile are targeted with new bactericidal chemical entities to restore antibiotic susceptibility. II. Drug resistant Tuberculosis is addressed with a virulence blocker that boost and restore efficacy of Isoniazid. III. Chlamydia infections are treated with a standalone virulence blocker. All projects are in pre-clinical phase with in vivo validations ongoing.

The Presenter

Dr. Fritiof Pontén is CEO of QureTech Bio since 2014. In this role he has established the company within the anti-infective field. At BIO-Europe Spring 2016 he was awarded winner of StartUp Slam. He has a PhD in organic chemistry and a solid experience of pre-clinical drug development gathered during 17 years at AstraZeneca. He has been active in a wide range of drug project activities ranging from all discovery phases to late stage preclinical studies enabling First Time in Man and is co-inventor of AZD7009 and AZD1305, the first two fully non-proarrythmic oral drugs that went into man.

QuretechBio
Defeats bacterial virulence

Founded: **2010** Employees: **1 + 4 academic teams**
Location: **Umeå, Sweden**
Investors: **Funded by Umeå Biotech Incubator and the founders**
Market: **Bring lifesaving new treatments for serious infectious diseases to the clinic within 3 year to meet the threat of antibiotic resistant infections caused by Enterococcus faecalis, Streptococcus aureus, Clostridium difficile or Mycobacterium tuberculosis.**

QureTech Bio AB
Tvistevägen 48C, 907 36 Umeå, Sweden
Tel.: +46 708 199379
Web: www.quretech.com

Contact: Dr. Fritiof Pontén, CEO
Mail: fritiof.ponten@quretech.com

Juvabis GmbH

Company Profile

Juvabis discovers and develops novel antibacterial therapeutics that are characterized by bactericidal potency against gram-positive and gram-negative pathogens including CRE and gonococci; full activity against all currently known resistance mechanisms; and a superior safety profile. In strong partnership with the IMI ENABLE program, clinical phase I studies are planned to begin in 2018. Our proprietary technology platform and chemical expertise continuously strengthen and diversify the Juvabis portfolio of leads that currently undergoes rigorous preclinical evaluation.

The Presenter

Dr. Sven Hobbie has been widely recognized as an accomplished translational researcher in infectious diseases, with more than 15 years of hands-on experience in antimicrobial drug discovery and early preclinical development. Prior to founding Juvabis, Sven has been a co-founder in two startup companies and has worked for the University Hospital of Zurich, Visterra Inc, and the MIT, for which he helped establishing infectious diseases research facilities in Singapore. Prior to graduating with a PhD from the ETH Zurich, Sven studied molecular microbiology in Germany, the US, and Switzerland.

Juvabis

Founded: **2015** Employees: **5**
Location: **Fürigen, Switzerland**
Investors: **Seeking investors**
Market: **Antibacterial Therapeutics**

Juvabis GmbH
Mettlenstrasse 14, 6363 Fürigen, Switzerland
Tel.: +41 41 780 1643
Web: www.juvabis.com

Contact: Dr. Sven N. Hobbie, CEO
Mail: sven.hobbie@juvabis.com

Omnix Medical

Company Profile

Omnix Medical is developing an arsenal of novel antibiotic agents against drug resistant bacteria. Its technology is based on the innate immune system of insects combatting bacteria in their surroundings. These insects use antimicrobial peptides which physically damage the bacterial membrane with no toxic effect to eukaryotic cells. The peptides' unique mechanism of action makes it very difficult for bacteria to develop resistance or tolerance. The major obstacle barring the use of these peptides, is their high sensitivity to proteolytic degradation which renders them unstable and has hindered them for therapeutic applications. Omnix's proprietary technology utilizes biochemical engineering to overcome this instability and allow for the commercialization of soluble, stable, safe and highly potent novel antimicrobial peptides.

The Presenter

Dr. Moshik Cohen-Kutner graduated from Hebrew University, Jerusalem. He received a PhD from the faculty of natural sciences in molecular and structural biochemistry. He has published numerous articles and was awarded prizes/scholarships. Dr. Kutner is an expert in peptide design for clinical applications. Prior to Omnix, Dr. Kutner founded the Junior Stuff Research and Teaching Assistants Organization. Dr. Kutner is a co-founder, the CEO and a member of the Board of Directors of the company.

Omnix Medical

Founded: **2015** Employees: **4**
Location: **Jerusalem, Israel**
Investors: **partnered with VLX Ventures**
Market: **The focus is on developing a treatment for infections involving gram-negative resistant pathogens, in particular the ESKAPE bacteria: K. pneumonia spp, A. baumannii, P. aeruginosa and Enterobacter spp. Omnix's molecules are being developed for systemic administration in serious hospital acquired infections.**

Omnix Medical
High-Tech Village Givat Ram Campus, P.O Box 39158, Jerusalem 91391
Tel.: +972 2 655 3333
Web: http://vlx.co.il/project/omnix-medical/

Contact: Dr. Moshik Cohen-Kutner, CEO
Mail: moshik@omnixmedical.com

Notes

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BIOCOM AG | Lützowstraße 33–36 | 10785 Berlin | Germany
www.biocom.de | Tel. +49 (0)30 264921-0 | Fax +49 (0)30 264921-11

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The Swiss Biotech Day is the leading biotechnology conference in Switzerland.

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Contact and further information:

BIOCOM AG
Lützowstrasse 33–36
10785 Berlin / Germany
Tel.: +49-30-26 49 21-0
Fax: +49-30-26 49 21-11
events@biocom.de
www.biocom.de